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Vaporizers, Humidifiers, and OTC Inhalant Products

— Thomas A. Gossel
— J. Richard Wuest

Staying on Top in the Real World: Honors Day Address

— Madeline Feinberg

Commentary: Government Thieves

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Biotechnology: What is it? How is it Done?

The Compounder's Corner

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Timely Topics: Alzheimer's Disease, Part I

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THE MARYLAND PHARMACIST

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Guest Message

A letter to the editor in the October 23, 1986 *New England Journal of Medicine* concerning a pharmacist advising a patient may evoke controversy over pharmacists counseling patients. The Massachusetts physician who wrote the letter reported that his patient had stopped taking her Quinidex after the pharmacist notified her that his computer showed Quinidex was incompatible with the Lanoxin she was also taking.

"I hope something can be worked out between the medical profession and pharmacists to prevent this dangerous type of druggist-patient interaction," the physician wrote. The editors headlined this letter, "More Physician-Pharmacist Cooperation Needed."

The importance of physician-pharmacist cooperation in counseling patients is why *USP DI* was founded. It was believed that USP, as a bi-professional, physician-pharmacist organization, could advocate, generate and foster such cooperation; and perhaps more to the point, if a Pharmacy organization attempted to do the same thing it would be bound to raise misunderstandings, resentment and opposition from Medicine.

As was stated in the Foreword of the first edition of *USP DI* in 1980: "Prescribers and dispensers need a common database in order not to confuse the patient. Physicians and dentists need to know what they can expect of the nurse and the pharmacist; and the pharmacist and the nurse need to know what the physician and the dentist expect them to consider telling the patient as they dispense and administer the prescribed drugs."

The fact the *USP DI* patient information is the database for the American Medical Association's Patient Medication Instruction sheets (PMIs), the American Academy of Family Physicians' DUET program, and the National Association of Retail Druggists' Patient Information Leaflets (PILs) is evidence that the national associations are trying hard to coordinate educational efforts on behalf of the patient.

Now, let's see how *USP DI* would help a pharmacist and physician handle a digoxin-quinidine interaction.

The physician could give the patient the AMA PMI or the USP patient drug education leaflet or photocopy the AAFP DUET page of the *USP DI Volume II* page for the digoxin and the quinidine. He could point out that the drug interaction is listed and explain that he was taking it into account; further, that the patient should not be perturbed if the pharmacist provided the NARD PILs or the USP patient drug education leaflets or photocopies of the *USP DI Volume II* pages which list this drug interaction.

The pharmacist could respond to his computer alert by looking in *USP DI Volume I* for either of the two drugs involved. There he would see that the rationale for listing the digoxin-quinidine interaction is that "concurrent use may result in substantially increased serum concentrations of digoxin." And that's where professional judgment comes in. As the preface to *USP DI* points out, the pharmacist must take "into account the best interests of the patient, the request of the prescriber, or the particular circumstances involved." If the same physician is prescribing both drugs, presumably the patient is being monitored for the results of this interaction. If there were any doubt, and certainly if the drugs are being prescribed by different physicians, the situation should be checked out with the prescriber(s). Certainly, it is not a case where written information for the patient suffices alone.

The continuously revised *USP DI* is prepared as a tool for you to use in consulting with your patients and your patients' physicians. *Volume II, Advice for the Patient,* is the best effort at any point in time of the nationwide USP network of physicians and pharmacists (and consumers) to put drug use information into plain language. The leaflets are abridgements of that information to fit onto a convenient, standard-size sheet. *Volume I, Drug Information for the Health Care Provider,* provides you with the technical backup to your consultation.

The continually increasing public interest in drug use information, spurred by the National Council on Patient Information and Education, the Food and Drug Administration, and the professions themselves, will require increasing attention to coordination between local physicians and pharmacists.

William M. Heller,

EXECUTIVE DIRECTOR, USP

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Editor's Note:
See page 13

SCOPE

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. III, NO. 12

Advising Consumers on Vaporizers, Humidifiers, and OTC Inhalant Products

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Goals

The goals of this lesson are to:

1. discuss the role of environmental humidity in maintaining maximal health;
2. explain basic actions of, and compare and contrast vaporizers and humidifiers; and
3. comment on OTC products intended for use with vaporizers.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from MERRELL DOW PHARMACEUTICALS INC.
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Objectives

At the conclusion of this lesson, the successful participant will be able to:

1. explain differences between the actions, beneficial and otherwise, of vaporizers and humidifiers;
2. suggest how to correct vaporizer malfunctions by modifying water ion composition;
3. cite specific OTC inhalant products that are used in or along with vaporizers; and
4. provide pertinent consumer advice for proper use of vaporizers, humidifiers, and OTC inhalant products.

Maintaining proper humidification of environmental air is important for assuring normal functioning of the body's physiologic systems and promoting good health. Two areas that are dependent on a proper environmental humidity level are the skin and respiratory system.

When humidity is too low, skin dries and cracks, and loses its resistance to penetration by foreign chemicals and microbes. The body's first line of defense is, therefore, compromised. Likewise, when air is too dry, respiratory passages become irritated and inflamed, and symptoms such as coughing, hoarseness, and sore throat appear.

Pharmacies remain a major source of vaporizers and humidifiers for the public. Most consumers view the pharmacist as an authority on these appliances.

This lesson discusses the importance of maintaining proper environmental humidity. It compares and contrasts functions, operations, benefits and reported problems of vaporizers and humidifiers. It also evaluates OTC volatile inhalant products marketed for use with vaporizers. Consumer advice concerning proper use is presented.

Importance of Proper Humidification

Absolute and Relative Humidity. Two terms that relate to moisture content of air are absolute and relative humidities. *Absolute* humidity expresses the amount of moisture present in a unit volume of air. *Relative* humidity measures the moisture content in air compared to the maximum quantity that would saturate it at any given temperature.

For example, when air contains half the moisture that it is capable of holding at a specific temperature, the relative humidity is 50 percent. Most individuals begin to feel uncomfortable when relative humidity decreases to below 25 percent. The pulmonary system functions best when relative humidity approximates 100 percent at body temperature.

Warm air can hold more moisture than cold air. In general, humidity is higher during the summer than fall and winter. During the winter months when the outside temperature is colder, air cannot contain the same quantity of moisture and the relative humidity drops.

Air inside a home that is artificially heated is likewise deficient in moisture content. The relative humidity of furnace-heated air can drop to below 10 percent. When this occurs, persons within the environment display symptoms of respiratory irritation, itching, and general discomfort.

So, relative humidity can also be described in terms of a "comfort index." The greater the value, the more comfortable an individual will be.

The body's humidification system consists of the nose, nasal passageways, the trachea and upper (proximal) sections of the bronchial tubes. Air entering the nose is heated by a rich supply of blood capillaries present in the nasal mucosal layer.

Even a cold nose on a winter day adds some warmth and moisture to inspired air. As this air descends to the warmer tracheal levels, more moisture and warmth are added. By the time air reaches the lungs, it is warmed close to body temperature, and its moisture content is approximately 99.5 percent saturated.

With expiration, the body rations its moisture. As expired air moves across progressively cooler respiratory passageways, it deposits moisture on these walls. This is one reason the nose may drip during periods of rapid breathing in cold weather. Its membranes, while warm in general, are still cooler than other respiratory passages. Therefore, it collects more fluid.

Cilia. Cilia are moving, hair-like protoplasmic protrusions located in the posterior portions of the nasal passageways. They move in a wave-like rhythm to propel foreign substances (e.g., infectious microorganisms associated with the common cold and influenza) upward and out of the respiratory system. They are able to do this because they are blanketed in a layer of mucus which normally is extremely rich in water content.

Cilia also add moisture to inspired air before it reaches the lungs. To achieve this, nasal mucosa must produce approximately one liter of fluid each day.

The respiratory mucus layer will dry and become overly viscous when relative humidity drops too low. Ciliary propulsion is hindered and mucus accumulates. This serves as an excellent culture medium for microbial growth. So, when the humidity is too low, an important normal defense mechanism of the respiratory system is lost. In fact, this area has now been converted to a breeding ground for microbes that may cause respiratory infections.

There is considerable evidence accumulated to date that proves that a person's incidence of upper respiratory infection increases when he is repeatedly exposed to low relative humidities. Twenty percent of all illnesses involving the nose and upper respiratory tract, sinus, and nasal pharynx are reportedly due to insufficient moisture in inhaled air.

The best means to assure that nasal mucus remains at its proper viscosity, and that cilia remain active is to increase humidification of air in the individual's environment. This can be readily and inexpensively achieved by using a vaporizer or humidifier.

Vaporizers

A vaporizer basically consists of a bowl to hold water, two electrodes which are surrounded by a plastic sheath open at the bottom, and a cover over the bowl that has an opening to emit steam (Figure 1). The electrodes and sheath are immersed in the water. There is usually a cup or depression in the cap at the point where the steam emerges. Volatile inhalant substances (Table 1) can be placed within it to be dispersed into the air along with steam.

To operate properly, vaporizers rely on minerals in tap water. In their ionized form, they complete an electric circuit between the electrodes. Water is heated and soon boils within the surrounding tube forming steam. The steam escapes into the atmosphere through the opening in the top of the unit. If the water level drops below the electrodes, the electrical circuit will be broken and steaming ceases.

As stated above, vaporizers are strongly dependent on the mineral content of water for activity. Two problems relating to mineral concentration may occur. In areas with excessive mineral content (hard water), malfunction is common. Steam flow will be erratic, tending to emit in spurts. The water may foam and even spill out of a filled bowl. When this occurs, tap water should be diluted with distilled water; the ratio should be adjusted appropriately.

TABLE 1
Substances That May Be Used with a Vaporizer
Inhalants
Benzoin, Compound Tincture
Benzoin, Tincture
Camphor Spirit
Eucalyptus Oil
VapoRub Ointment (Vicks) (camphor, menthol, turpentine spirit, eucalyptus oil, cedar leaf oil, myristica oil, thymol)
VapoSteam Liquid, (Vicks) (eucalyptus oil, camphor, menthol, tincture of benzoin)
Cleaner
Vap-O-Clean (Devilbiss) (citric acid)

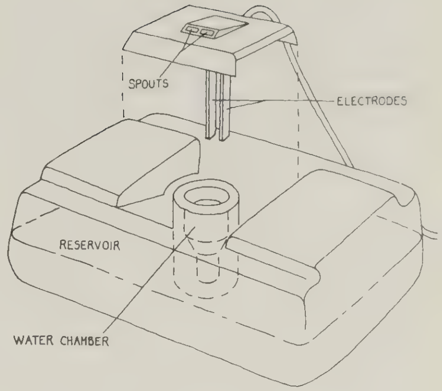

Figure 1. Vaporizer

In areas devoid of minerals, water is soft and steam production may be slow or absent. If the vaporizer does not begin producing steam within 10 to 15 minutes, a quarter-teaspoonful of borax or baking soda should be added to the water to increase its electrical conductivity. Table salt should not be used since it promotes excessive corrosion of the electrodes.

Properly functioning, a vaporizer should begin to emit steam within 2 to 3 minutes. It should produce a steady flow in 15 to 30 minutes.

Mineral deposits can form on electrodes and decrease a vaporizer's efficacy. The unit should, therefore, be periodically dismantled and cleaned. The electrodes should be scraped free of deposits or soaked in a solution of vinegar for several hours. A commercially available OTC product (Table 1) for this purpose can also be used.

Humidifiers

A humidifier (Figure 2) differs from a vaporizer in that it produces a cool mist rather than hot steam. Humidifiers have moving parts.

Water is drawn by a motor-driven impeller through a chamber. It is thrust against a spinning disk that

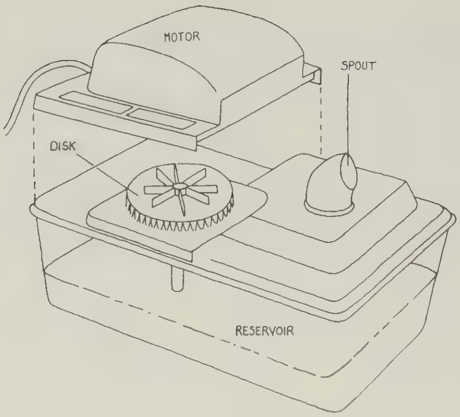

Figure 2. Humidifier

has a comb-like surface. This reduces the water particle size to tiny droplets which are discharged by the centrifugal force of the spinning disc into the atmosphere. The droplets readily evaporate, and thereby increase humidity in the room. Humidifiers do not use volatile inhalant medicinals. These substances are likely to ruin the unit.

Humidifiers are not affected by the hardness or softness of water used in them. In fact, humidifiers, but not vaporizers, can operate with totally distilled water. Humidifiers will also continue to run regardless of the presence or absence of water in the reservoir, and no harm will come to them if the reservoir runs dry. This means that most units must be turned off manually. Some of the more expensive models are equipped with humidostats which measure moisture in the air and shut the unit off automatically when the proper humidity has been reached.

Which is Better — Steam or Cool Mist Moisture?

Opinion is divided as to whether warm steam or cool mist moisture is more "healthy." Proponents of both systems claim definite advantages of one over the other. Neither side has yet gathered sufficient information to prove its argumentative position.

It is the end result, increased environmental *moisture*, that is important. The means by which this is accomplished is irrelevant to personal health. Advantages and disadvantages of the appliances relate to other issues.

Steam Vaporizers. Those in favor of steamers argue that humidification of the room is achieved more rapidly with these appliances. Particle size of steam molecules is smaller than particles of cool moisture. However, if the unit is operated continuously, this should not be important.

They argue further that since the water is first boiled before added to the air, it is relatively sterile. Most people agree that the units are less noisy than humidifiers and generally cost less to purchase. Vaporizers have an automatic shut-off feature, in that they stop working when the water is gone. Only the more expensive humidifiers have this feature.

Cool Mist Humidifiers. Proponents claim that humidifiers produce more rapid humidification since moisture is added to the air as soon as the unit is activated. There is no need to wait for the water to boil. But most vaporizers usually begin to emit steam within 2 to 3 minutes, so this argument has questionable merit.

Cool mist vapor does not increase the heat level within the room. It, therefore, reportedly causes less damage to walls and furniture.

Proponents of humidifiers frequently claim that vaporizers loosen wallpaper. But in consumer tests where this has been studied, it has not been shown to be a problem.

Since humidifiers demand less electricity to operate, their overall usage cost is less than that for vaporizers. However, the initial purchase price of humidifiers is higher.

Humidifiers are noisy to operate. The typical drone, hiss, or whirling sounds of a running humidifier may be bothersome to some individuals, but reassuring to others in that something is being done.

Volatile Inhalation Medications

The volatile substances shown in Table 1 are available for use with vaporizers. They should not be used with humidifiers.

It is questionable whether these substances impart significant therapeutic value to the patient. They do emit a pleasant "medicinal" smell to the air, and this "placebo" effect may be beneficial in comforting an anxious parent of a small child with congested, noisy, or labored breathing. In actuality, the child profits from the moisture; the parent benefits from the odor.

However, some consideration should be given to the fact that camphor/menthol-containing ointments rubbed on the chest have been proven to be safe and effective antitussives due to the inspired volatile ingredients. If the inhalant reaches the same concentration as that emitted from the applied ointment, the inhalant may be helpful in alleviating cough.

Consumer Advice

There is considerable evidence that moisture helps alleviate inflamed mucous membranes of the nasal pharynx and respiratory tract. Patients with colds, allergies or sinusitis will, therefore, benefit from increased atmospheric moisture. Their mucus-clogged nasal passageways will be easier to clear when a vaporizer or humidifier is used.

The appliance will also be beneficial in helping to lessen the incidence and severity of cough and sore throat, and, in general, will make breathing easier. Consumers who suffer frequent or recurring respiratory distress should be apprised that purchasing any device to increase air moisture content is undoubtedly a wise investment.

Consumers frequently call all vaporizer and humidifier units a "vaporizer." In fact, few consumers are reportedly able to distinguish correctly between them.

When advising consumers on their use, pharmacists should first make sure that the buyer knows which unit he wants and how to correctly operate it. Whether a consumer chooses a vaporizer or humidifier, the level of moisture in the air will be increased.

Consumers in one study were asked to comment on which safety features of vaporizers and humidifiers they condsidered to be most important. The most desired features included a locked cover, automatic shut-off switch, and all-night operating capacity.

A unit that has a minimum of one gallon (vaporizer) capacity or two gallon (humidifier) capacity water reservoir is best to recommend so that it will indeed provide the moisture necessary for all-night operation.

When in operation, it is best to place a vaporizer on the floor rather than on furniture. Direct forceful steam may ruin furniture and the unit may be more easily tipped over. If a vaporizer or humidifier must sit on furniture, a towel should be placed underneath it. The units collect moisture on their sides. Droplets of water fall from both steam and cool mist which may damage unprotected furniture.

Unless specifically directed by a physician, steam flow should not be directed toward the patient, but toward an open area so that air in the entire room may be uniformly moistened. Individuals should be warned not to insert a finger into the water supply of an operating vaporizer to test its temperature. The electrical plug must always be pulled from the outlet before working on the unit.

Vaporizers and humidifiers should be guaranteed against defects. Units that do not meet minimum standards of Underwriter's Laboratories should be avoided. Modern safety features include a solid base so that the vaporizer will not tip even when inclined at a 30° angle, regardless of the quantity of water in the bowl. Water temperature in the reservoir should not exceed 130°F. It should have a locked cover to guard against spilling if the unit should accidentally tip.

Vaporizers and humidifiers should be thoroughly cleaned and dried after use. Water should not be allowed to stand in the reservoir if the unit is not in operation. Bacterial and fungal organisms may grow in it and be spread into the air when the unit is later activated. A condition known as *humidifier fever* may result in susceptible persons. Vaporizers are less likely to spread infection because microorganisms cannot survive in boiling water. But they can and do grow in the cooler parts of the plastic. If a vaporizer or humidifier is used only a few hours each day, fresh water should be added each time before operating the unit.

Award Established

A new award for leadership by a young pharmacist has been established by Phi Delta Chi Pharmacy Fraternity. To be awarded for the first time in 1987, the Albert B. Prescott Leadership Award will be given annually to a young pharmacist no more than 10 years into his or her career. The recipient will deliver a scholarly lecture on issues such as pharmacy as a profession, leadership, or future trends in pharmacy practice or education.

Albert B. Prescott was a maverick in the late 1800s because of his advocacy for an academic basis for pharmaceutical education. Founder and dean of the College of Pharmacy at the University of Michigan, Prescott nurtured his idea for nearly 25 years before the rest of the profession caught up with his vision. In 1900, Prescott was the first president of the American Association of Colleges of Pharmacy, and many schools date their founding from around the turn of the century. This chemist, educator, and leader of pharmacists was also instrumental in the founding of Phi Delta Chi at the University of Michigan in 1883, and he was the advisor to the Alpha Chapter and the first honorary Brother of the Fraternity. The recipient of the Prescott Leadership Award must:

1. Have entered the profession of pharmacy (i.e., graduated from pharmacy school) less than 10 years before nomination.
2. Have demonstrated exemplary leadership qualities as a student and young pharmacist indicative of someone likely to emerge as a major leader in pharmacy over the course of his or her career.

Nominations for the first Prescott recipient are now being accepted. These should be sent to the chairman of the selection committee, Lawrence C. Weaver, Ph.D., at the Pharmaceutical Manufacturers Association, 1100 15th Street, NW, Washington, DC 20005. The deadline for receipt of nominations is January 15, 1987. A copy of the nominee's curriculum vitae is requested.

Phi Delta Chi Pharmacy Fraternity comprises chapters at 48 colleges of pharmacy across the country. Nearly 33,000 men and women have been proud to call themselves Brothers of Phi Delta Chi and Leaders in Pharmacy. For more information about the Fraternity, contact the National Office at 2300 Ninth Street South, Suite 517, Arlington, VA 22204; 703/920-3700.

Important Drug Abuse Telephone Numbers

Addict Referral and Counseling Center	**366-1717**
Balt. City Health Dept.	**396-3764**
Balt. City Police Drug Hotline	**685-DRUG**
Balt. County Drug Abuse Coordinator's Office	**494-3828**
Balt. County Police Narcotics Division	**494-2170**
Cocaine Dependency Unit	**788-2145**
Community Counseling and Resource Center (Cockeysville)	**628-6120**
Maryland State Police Drug Hotline	**1-800-492-TIPS**
Md. State Drug Abuse Administration	**225-6910**
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"TIMELY TOPICS"

A regular monthly feature sponsored by the Parke-Davis Center for the Education of the Elderly and the Elder-Health Program, University of Maryland School of Pharmacy. At the conclusion of each series, a sample "Elder-Ed" talk for presentation to the community will be outlined.

PHARMACOLOGIC CONSIDERATION IN THE TREATMENT OF ALZHEIMER'S DISEASE

Part I

by Peter P. Lamy, PhD
Ilene H. Zuckerman, PharmD

DEMENTIA

Definition: Dementia is a clinical syndrome involving reduced intellectual functioning with impairment in memory, language, visuospatial skills, and cognition (including mathematics, abstraction, and judgment).

Prevalence: Reliable estimates of the prevalence of dementia or Alzheimer disease (AD) are not available for persons under age 65. Between three and five percent of people over the age of 65 have impairment of memory, intellect, orientation, and personality (approximately 1.3 million?). A similar proportion have milder dementia. Most elderly dementia patients (70%) are community residents.

Risk Factors: Dementia is increasingly common with advancing age (note: 80% of people over the age of 80 are *not* demented). World-wide, there were 214 million persons aged 60 and over in 1950. By the year 2050, there will be one billion, a four-fold increase. In the United States, among the fastest-growing segment of the population, those 85 years old and older, those 95 and over are increasing most rapidly in number. Thus, the number of people afflicted with dementia is expected to increase significantly, perhaps to 10 million by the year 2050 (Tables I, II).

There are no other known risk factors for dementia and, in particular, Alzheimer disease other than old age. Some risk factors have been suggested, including family history, family history of Down's syndrome or lymphomas, Down's syndrome, head injury, and thyroid disease. Other hypothesized risk factors include low social class, low premorbid intelligence, history of affective disorder, degenerative eye disease, and alcohol abuse.

Need: Demented patients need around-the-clock surveillance and care. They are prone to crises, often because of a worsening of their condition (common: confusional states).

Types of Dementia: There are several treatable dementias (approximately 20% of all cases). Table III lists those.

Presented at the meeting of the Health and Education Council "Meeting the Challenge of Alzheimer's Disease and Related Disorders", Baltimore, Maryland, 1986

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, School of Pharmacy, Professor, Epidemiology & Preventive Medicine, School of Medicine, University of Maryland at Baltimore.

Dr. Zuckerman is Assistant Professor, Department of Clinical Pharmacy, School of Pharmacy.

TABLE 1

Probability of Selected Medical Conditions as the First Reported Cause of Chronic Disability among Disabled Persons, 85 Years and Older: United States 1982

Condition	Percent
Dementia	19.43
Arthritis	16.75
Peripheral Vascular Disease	14.88
Cerebrovascular Disease	12.86
Hip & Other Fractures	8.81
Ischemic Heart Disease	1.88
Hypertension	1.38
Diabetes	1.01
Cancer	.91
Emphysema & Bronchitis	.26

TABLE 2

Change over Age (from 65 to 74 to 85+) in the Probability that a Chronically Disabled Person Reports a Selected Medical Condition as a Cause of Disability

Condition	Percent 65 to 74	Percent 85+	Ratio
Dementia	3.28	34.60	10.55
Arthritis	36.88	34.66	0.94
Peripheral Vascular Disease	33.83	33.68	1.00
Cerebrovascular Disease	30.72	26.98	0.88
Hip & Other Fractures	29.41	18.27	0.62
Ischemic Heart Disease	6.01	3.27	0.54
Hypertension	13.87	8.53	0.61
Diabetes	10.21	3.29	0.32
Cancer	6.44	1.93	0.30
Emphysema & Bronchitis	8.73	1.63	0.19

Health Care Financing Administration, 1982 National Long Term Care Survey

There are several dementias that cannot be treated, most notably primary degenerative dementia (PDD), also called senile dementia, senile dementia of the Alzheimer type (SDAT), Alzheimer disease (AD), or organic brain syndrome. (Note: this is not mild memory impairment, sometimes called benign senescent forgetfulness).

TABLE 3

- Intracranial conditions
  - multi-infarct dementia (MID)
  - extrapyremidal disorders (EPS)
  - hydrocephalus
  - subdural hematomas
  - intracranial neoplasms
  - infections
- Chemical intoxications
  - drugs
  - metals
  - industrial waste
- Depression
- Systemic disorders
  - cardiovascular
  - hepatic
  - endocrine
  - renal
  - nutritional deficiencies
  - collagen-vascular diseases

Alzheimer Disease

AD and SDAT is a disorder of unknown etiology. It is a pathological diagnosis based on the presence of neurofibrillary tangles and plaques throughout the cerebral cortex. No objective, unequivocal diagnostic procedure is available to detect AD early or to quantitate cognitive decline. The etiology and pathogenesis of the disorder is still unclear, but a number of factors appear to be involved (Table IV). Based on some of these, some treatment modalities have arisen.

TABLE 4

Possible Causes of Alzheimer Disease

- Genetic factors
- Abnormal protein models
- Infectious agents
- Toxins
- Blood flow disorders†
- Cholinergic hypothesis†
- Multiple factors

† Precursors of treatment modalities

Of note is that an inorganic substance composed of aluminum and silicon is present in the plaques of AD patients. This led to the suggestion that aluminum may be a causative factor of AD (antacid use?), but this theory remains very controversial. Recently, large amounts of a protein with a molecular weight of 60,000 have been found in the nerve cells of the brains of AD patients, a protein that does not seem to be a component of the normal brain. The role of increased cholinergic activity in cortisol hypersecretion, abnormal dexamethasone suppression, depressive symptoms, motor retardation, and sleep EEG in AD patients has also been described recently.

Drug Use in AD Patients: A Cautionary Note

Drugs commonly cause intellectual impairment. Persons with pre-existing brain damage or dementia, chronic medical illness and increased age are at high risk to delirium. Any cause of impaired CNS functioning or reduced consciousness predisposes to delirium because the patient is vulnerable to direct precipitators of delirium.

Pharmacologic agents that can induce delirium include alcohol, analgesics, anticholinergics, antidepressants, antihistamines, antiparkinsonian agents, cimetidine, digitalis, diuretics, neuroleptics, and sedative/hypnotics. Other precipitators of delirium are cardiovascular disease, infections, metabolic disorders, and trauma. Since many of these agents are prescribed for AD patients and since AD patients may develop the disorders listed, it is important to be able to distinguish between delirium and dementia.

Delirium develops abruptly, is non-progressive, of short duration. It has a precise onset and patients will present with fluctuating consciousness.

In contrast, dementia develops slowly, is progressive, and is present for a prolonged period of time. People are uncertain about its onset, and patients rarely present with altered consciousness.

(Part II is entitled "Drugs for Treatment of Alzheimer's Disease.")

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Brief Summary

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WARNINGS: Heart Failure: ISOPTIN should be avoided in patients with severe left ventricular dysfunction (see DRUG INTERACTIONS). Patients with milder ventricular dysfunction should, if possible, be controlled before verapamil treatment. Hypotension: ISOPTIN (verapamil HCl) may produce occasional symptomatic hypotension. Elevated Liver Enzymes: Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Periodic monitoring of liver function in patients receiving verapamil is therefore prudent. Accessory Bypass Tract (Wolff-Parkinson-White): Patients with paroxysmal and/or chronic atrial flutter or atrial fibrillation and a coexisting accessory AV pathway have developed increased antegrade conduction across the accessory pathway producing a very rapid ventricular response or ventricular fibrillation after receiving intravenous verapamil. While this has not been reported with oral verapamil, it should be considered a potential risk. Treatment is usually D.C.-cardioversion. Atrioventricular Block: The effect of verapamil on AV conduction and the SA node may cause asymptomatic 1st degree AV block and transient bradycardia. Higher degrees of AV block, while infrequent (0.8%), may require a reduction in dosage or, in rare instances, discontinuation of verapamil HCl. Patients with Hypertrophic Cardiomyopathy (IHSS): Although verapamil has been used in the therapy of patients with IHSS, severe cardiovascular decompensation and death have been noted in this patient population.

PRECAUTIONS: Impaired Hepatic or Renal Function: Verapamil is highly metabolized by the liver with about 70% of an administered dose excreted in the urine. In patients with impaired hepatic or renal function verapamil should be administered cautiously and the patients monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacological effects (see OVERDOSAGE).

Drug Interactions: Beta Blockers: Concomitant use of ISOPTIN and oral beta-adrenergic blocking agents may be beneficial in certain patients with chronic stable angina or hypertension, but available information is not sufficient to predict with confidence the effects of concurrent treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities. Digitalis: Clinical use of verapamil in digitalized patients has shown the combination to be well tolerated if digoxin doses are properly adjusted. However, chronic verapamil treatment increases serum digoxin levels by 50 to 75% during the first week of therapy and this can result in digitalis toxicity. Upon discontinuation of ISOPTIN (verapamil HCl), the patient should be reassessed to avoid underdigitalization. Antihypertensive Agents: Verapamil administered concomitantly with oral antihypertensive agents (e.g., vasodilators, angiotensin-converting enzyme inhibitors, diuretics, beta blockers, prazosin) will usually have an additive effect on lowering blood pressure. Patients receiving these combinations should be appropriately monitored. Disopyramide: Disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration. Quinidine: In patients with hypertrophic cardiomyopathy (IHSS), concomitant use of verapamil and quinidine resulted in significant hypotension. There has been a report of increased quinidine levels during verapamil therapy. Nitrates: The pharmacologic profile of verapamil and nitrates as well as clinical experience suggest beneficial interactions Cimetidine: Two clinical trials have shown a lack of significant verapamil interaction with cimetidine. A third study showed cimetidine reduced verapamil clearance and increased elimination to 1/2. Anesthetic Agents: Verapamil may potentiate the activity of neuromuscular blocking agents and inhalation anesthetics. Carbamazepine: Verapamil may increase carbamazepine concentrations during combined therapy. Rifampin: Therapy with rifampin may markedly reduce oral verapamil bioavailability. Lithium: Verapamil may lower lithium levels in patient on chronic oral lithium therapy. Carcinogenesis, Mutagenesis, Impairment of Fertility: There was no evidence of a carcinogenic potential of verapamil administered to rats for two years. Verapamil was not mutagenic in the Ames test. Studies in female rats did not show impaired fertility. Effects on male fertility have not been determined. Pregnancy (Category C): There are no adequate and well-controlled studies in pregnant women. ISOPTIN crosses the placental barrier and can be detected in umbilical vein blood at delivery. This drug should be used during pregnancy, labor, and delivery, only if clearly needed. Nursing Mothers: ISOPTIN is excreted in human milk, therefore, nursing should be discontinued while verapamil is administered. Pediatric Use: Safety and efficacy of ISOPTIN in children below the age of 18 years have not been established.

ADVERSE REACTIONS: Constipation 8.4%, dizziness 3.5%, nausea 2.7%, hypotension 2.5%, edema 2.1%, headache 1.9%, CHF/pulmonary edema 1.8%, fatigue 1.7%, bradycardia 1.4%, 3° AV block 0.8%, flushing 0.1%, elevated liver enzymes (see WARNINGS). The following reactions, reported in less than 1.0% of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain; they are mentioned to alert the physician to a possible relationship: angina pectoris, arthralgia and rash, AV block, blurred vision, cerebrovascular accident, chest pain, claudication, confusion, diarrhea, dry mouth, dyspnea, ecchymosis or bruising, equilibrium disorders, exanthema, gastrointestinal distress, gingival hyperplasia, gynecomastia, hair loss, hyperkeratosis, impotence, increased urination, insomnia, macules, muscle cramps, myocardial infarction, palpitations, paresthesia, psychotic symptoms, purpura (vasculitis), shakiness, somnolence, spotty menstruation, sweating, syncope, urticaria. Treatment of Acute Cardiovascular Adverse Reactions: Whenever severe hypotension or complete AV block occur following oral administration of verapamil, the appropriate emergency measures should be applied immediately, e.g., intravenously administered isoproterenol HCl, levarterenol bitartrate, atropine (all in the usual doses), or calcium gluconate (10% solution). If further support is necessary, inotropic agents (dopamine or dobutamine) may be administered. Actual treatment and dosage should depend on the severity and the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE: Treatment of overdosage should be supportive. Beta-adrenergic stimulation or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been used effectively in treatment of deliberate overdosage with verapamil Clinically significant hypotensive reactions or fixed high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including cardiopulmonary resuscitation.

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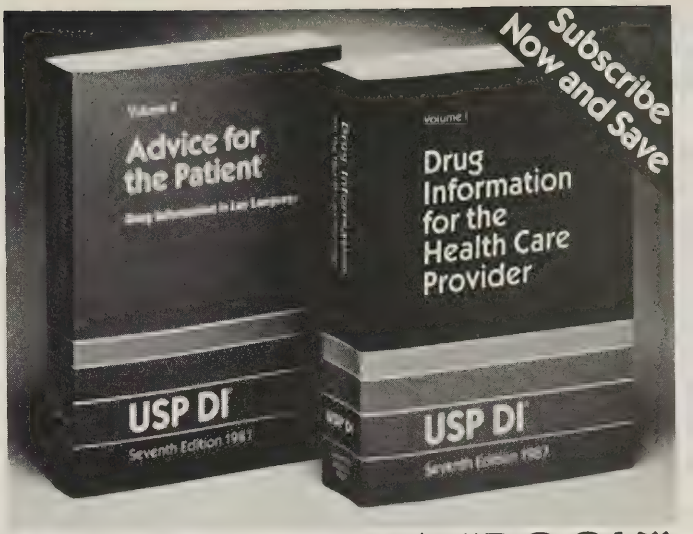

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STAYING ON TOP . . . IN THE REAL WORLD:

Honors Day, 1986

by Madeline Feinberg

I am delighted and honored to be invited to speak by the S.G.A. at today's ceremonies. What I have to tell you today, is about *a meeting* that took place more than 2 years, when many of you were sharpening your pencils and getting ready to take the P-CAT exams to get into pharmacy school.

It's about that meeting that took place at Project Hope headquarters in Millwood Virginia, back in March 1984. Some of the great *thinkers in health care* in America went to that meeting . . . to ponder a great question: Will there be such a thing as pharmacy in the year 2010. If so, what will it look like?

Now some of you may be thinking how *some of us up here* on the podium are going to look in the year 2010. Also you may be wondering if some of those people on the podium didn't lead you down the primrose path, back in the good ole 1980's. Maybe we are leading you down the Primrose Path, when it comes to pharmacy and your very-uncertain-future.

After all, look how fast things seem to change. When I was a kid, back in the 1940's, we had "*druggists*" *on every corner* in America. When you fell on the boardwalk in Brighton Beach, who helped pull the splinters out of your bottom? Right! The druggist. He was an establishment in the community, like he had been for the past 15 centuries. And now, in a mere 25 years, we think we may no longer have such a thing as a "pharmacist"?

Here's what some of those great thinkers in health care predicted in Millwood Virginia back in March 1984. They looked into their crystal ball and saw that more than half the medications we dispense today will be *over the counter:* the beta blockers, the calcium channel blockers, the H 2 -receptor antagonists, the diuretics, to name a few. Soon, they'll all be in Aisle 4 B, Madam. (Who needs a pharmacist?)

They saw that prescriptions would be dispensed by computers and robots. In fact, the Japanese have already developed a *robot* that will count, pour, lick and stick. But now it costs $60,000. Just wait, remember the VCR's? The price will drop. (Who needs a pharmacist?)

They also saw that patients will go to their doctors, not only to be *diagnosed,* but to get their subcutaneious osmotic pumps *refilled* and to get the implanted tablets *replaced* after 6 months. (Who needs a pharmacist?)

They didn't have to look too hard to see patients in 2010 (today's little kids), accessing their *computer data banks* for information on their diseases, their drugs, and yet, sending their orders directly to the centralized pharmacy at their place of employment for refills. The reordered medication would come right to their desks, via the *interoffice* mail? (Who needs a pharmacist?)

Of particular interest to that group hovering around the crystal ball, was the *decrease in morbidity and mortality* due to cancer and heart disease, thanks to new vaccines that had been discovered. (Less chronic disease?, Who needs a Pharmacist?)

They certainly didn't need a crystal ball to look at the population characteristics. No surprises there. Lots of "*elderly.*" Lots of elderly interested in staying *healthy,* getting involved in self care, interested in nutrition, exercise, preventive measures to prolong wellness.

Before this group would consider what pharmacy was going to look like in 2010, they had to consider how drugs would fit into the picture.

No doubt about it. Everyone agreed *drugs were going to be important in the 21st Century.* First they look back, for some perspectives. Back in the late 1940's, Americans spent *15¢* of their health care dollar on medications. Today we spend *6¢* of our health care dollar on medications. Drugs are a bargain! Simply because everything else is so expensive.

The group felt that drugs would continue to be a "*good buy*" in health care. One thing for certain, drugs would be an important component of health care.

They predicted that we would have a much *enhanced pharmacopoeia.* This would be in addition to the very sophisticated drug delivery systems that we will have: pumps, patches, time-release pills, intranasal sprays, liposomes, and vials of tailored monoclonal an-

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Delivered by MPhA Board Chairman Madeline Feinberg at the University of Maryland School of Pharmacy Student Honors Convocation, November 18, 1986.

tibodies. Drugs of the future would be more specific in drug action, more potent, more complicated, and more tied to basic biochemistry.

All the participants concluded . . . that if pharmacy is to survive, the pharmacist's broad knowledge base would define the profession of pharmacy. Pharmacists of the future must be informed to cope with and handle these drugs, not just with doses and administration, but with basic biochemistry. The bottom line . . . that scientific knowledge and expertise in knowing the drug product better be there, if pharmacy as we understand it today, is going to be there in the 21st Century. Which means, I think, you're studying has just begun!

But there's going to be more to it. You may be the one to design the gene therapy. And you may be the one to add the drug to the pump or implant matrix. Or you may be able to design the dosage form based on the prescribed specific rate of drug release. *But your ticket into the next Century—and whether you get in there or not—may be because you have assumed the role for monitoring drug therapy, for counseling patients, and for putting a human face on the sophisticated technologies of drug therapy.*

This should start to sound familiar. Because pharmacy educators have been knocking their heads (and perhaps yours as well) against the wall to get you to assume *the* role in monitoring drugs and counseling. We even offer you a *free trip to Chicago* and the APhA convention (is Chicago a prize, you ask?) if you will do a good job counseling a patient. You're not offered a free trip to Chicago to count to 100 and slap the label around the bottle.

If you let the "establishment" tell you that good pharmacy practice is *filling 200 or 300* plus scripts a day PERIOD! you're going to wind up on the unemployment lines in 2010. But if you have the guts and drive to be a professional, and not to be used, then you will have a fighting chance to stay in pharmacy.

You'll have to stay current on drugs. You've got to pick quality Continuing Education programs. Make use of your time. You've got to tell your school that you want the opportunity to *update your knowledge* on a regular basis, for graduate course work, and that you feel it is the School's responsibility to meet that need. They used to say that 5 years after you graduate, your knowledge is out of date. Its true. Keeping up is a constant struggle and we complain that we're falling behind. We mustn't let that happen.

But all this is a useless exercise in masochism and self-torture—all this studying, and "keeping up"—if you do not *flaunt your knowledge*. Talk to your patients. Talk to the physicians. Talk to the nurses. Talk to the discharge planners (do you know who they are. You better find out!). Talk to families, to caregivers, to politicians. Visit home health agencies and sell them your consultant services. Visit the retirement homes in your communities and sell them your pharmaceutical services. And keep an eye on your legislators in Annapolis. They need to know how important you are to the wellbeing of their constitutency.

There will be *plenty of competition* for you. The *Docs* are not seeing 6 figure incomes any more. *Nurse practitioners* want a piece of the action. So do the insurance companies and corporate America who is paying the health care bills. They'd like to cut down the 6¢ of every health care dollar to 5¢ or 2¢. If your services can be dispensed with, Tough!

So that's why I think you have a-very-uncertain-future. Not because drugs are not going to be important, but because they will be so important everyone will want a piece of their action, at a good price.

But, believe it or not, *you are the drug experts*. If you don't believe it, I suggest you do a rotation in long-term care and see what physicians prescribe for these residents in nursing homes. What about prescribing for the rest of us? They need you out there!!

Stay on top, like you are today. Stay involved. Squeaky wheels really get the grease. Be first in what you know, then tell everyone how great you really are! You need to have a big mouth too!

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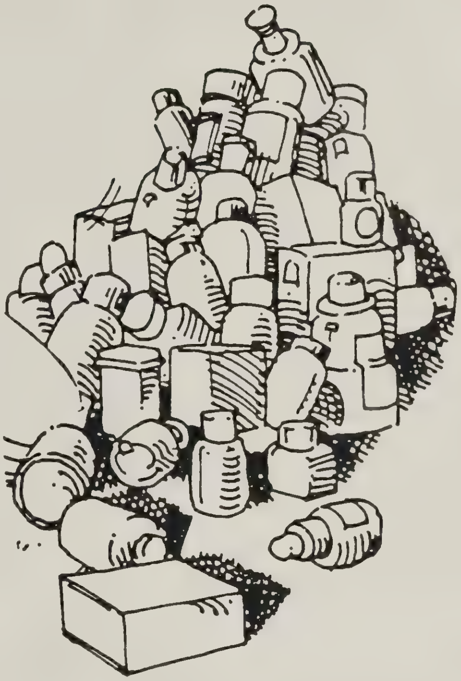

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Government Thieves

by Jim Dickinson

Government thieves. This is important. Go to your typewriter, word-processor or pencil as soon as you're done reading this. You'll see why.

First, though, ask yourself: Does Medicaid deserve a discount from pharmacy? If your answer is a firm, resounding "Yes!" please read no further.

"Discount" is the buzzword of the year. You remember how federal Medicaid discovered that pharmacies get prompt payment discounts off list price, and how Average Wholesale Price isn't the same as list, because of discount-type things.

Those pharmacies are getting away with murder, the feds said, in shock—we want those discounts! So they dreamed up schemes to confiscate them, telling their regional offices to go get 'em, by whatever means it took.

You remember how, last year, the south-west Medicaid region announced mandatory discounts, state by state, and how, while all the pharmacy groups went to the wall with a lawsuit in Washington, Texas got stuck with a discount off AWP that it's still living with.

The legal confrontation in Washington was an outstanding victory for pharmacy and its friends in industry who joined in—a rare, thrilling example of "united we stand, divided we fall."

But, when you're fighting the federal Medicaid bureaucrats, no win lasts for long.

These officials for over a decade have successfully defied law and order by refusing to yield to either political or judicial direction. They have a one-track mind. They duck their heads, turn their other cheek, stand their ground, step aside, dodge and weave—but they're always, always there. Blind, deaf and dumb, they stand there, right where they've always been like some giant tree stump, endlessly convinced of one thing and one thing only: pharmacies have got money that should be theirs.

Resuming—as you surely knew they would—their single-purpose campaign to dredge more money out of pharmacy, the federal Medicaid bureaucrats have devised three alternatives to their unfair and, finally, unworkable MAC-EAC program. These crafty new devils are called PhiP (Pharmacy Incentive Program), CIP (Competition Incentive Program) and Modified MAC. They *don't* offer more money to pharmacy!

They were rushed into the Washington bullpit for fast discussion and implementation before all the cost-savings analyses were completed. As these draft analyses slither out of their thinktanks now, we can begin to see a bottom line taking shape in them—it equals about a 10% discount off average "private pay" Rx retail prices.

Nothing is firm, sharp and distinct, mind you. These are "preliminary" figures, and "draft" analyses, you understand. It would be wrong to criticize them. They're just for discussion, while the final program is decided upon elsewhere!

The National Association of Chain Drug Stores in October rendered a signal service to pharmacy by commissioning University of Chicago Law Professor Paul M. Bator to report on all the laws that federal Medicaid has been twisting, if not breaking, in its dishonest profit-confiscation efforts.

Citing 42 CFR Sec. 447.204 in the Medicaid regulations where it says "The [state medicaid] agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients *at least to the extent that those services are available to the general population*" (emphasis added), Bator laid it out:

"Accordingly," he reported, "the regulations explicitly require that, to the extent that medical services to the 'general population' are conventionally provided by for-profit enterprises, these enterprises be reimbursed at a level 'sufficient to enlist' their participation in the Medicaid program—something that is manifestly impossible unless efficient providers are allowed to make a fair profit."

Bator noted that some pharmacies have refused to

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do business with Medicaid, and those that continue to do so are motivated by factors such as public-spiritedness or a desire not to incur adverse publicity by a refusal to serve the poor—"it must be acknowledged that there is substantial societal pressure on drug stores to participate in the Medicaid program."

It's entirely inconsistent with Medicaid's philosophy, Bator wrote, that non-Medicaid patients should subsidize Medicaid patients in the cost of their prescriptions, or that pharmacy's reasonable profits should be confiscated.

You know that Bator has put it on the line, right where it belongs. Government confiscation of private property is what it boils down to. It may be cloaked in legal garb, but it really is theft. Your money is being stolen by government thieves, even before you get it.

Now you know what to do with your typewriter, word-processor and pencil. Mail your views to Donald Newman—a former independent pharmacist, who surely understands. He's also the current Under-secretary at HHS (Room 614G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC. 20201).

I'm not sure about this, but he might have the power to make the federal Medicaid bureaucrats stop it. Nobody else has ever been able to tell them and make it stick, but it's worth a shot.

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1987 TAX DATES

The following are due dates for federal and state taxes that will most likely affect you or your organization. Taxes that are due four or more times during the year are identified by abbreviations explained below the chart. Note that if a tax is due on a weekend or holiday, the due date is advanced to the next business day, causing some taxes due the last of the month to be payable early in the following month.

January 1987

Tuesday, January 6	FD(a)
Thursday, January 15	FD(b), FI/SI
Wednesday, January 21	ST

February 1987

Monday, February 2	FQ, FU, FD(c), SQ, SU Employees' statements W-2 for amounts withheld in 1986 to be furnished by employer. Employer file federal unemployment tax Form 940 for 1986.
Wednesday, February 4	FD(a)
Monday, February 16	FD(b)
Monday, February 23	ST

March 1987

Monday, March 2	Forms W-2 "A" copies with transmittal form W-3 filed with Social Security Administration.
Wednesday, March 4	FD(a)
Monday, March 16	FD(b) Federal and state corporate income tax return due or you must pay estimated amount due and file for automatic 6 month extension. Interest will be paid on amount paid after March 16.
Monday, March 23	ST

April 1987

Friday, April 3	FD(a)
Wednesday, April 15	FD(b), FC, FI/SI, SC Federal and State Individual Income Tax due or you must pay estimated amount due and file for an automatic four month extension. Interest will be paid on amount paid after April 15. State personal property tax due.
Tuesday, April 21	ST
Thursday, April 30	FQ, FU, FD(c), SQ, SU

May 1987

Tuesday, May 5	FD(a)
Friday, May 15	FD(b)
Thursday, May 21	ST

June 1987

Wednesday, June 3	FD(a)
Monday, June 15	FD(b), FC, SC, FI/SI
Monday, June 22	ST

July 1987

Friday, July 3	FD(a)
Wednesday, July 15	FD(b)
Tuesday, July 21	ST
Friday, July 31	FQ, FU, FD(c), SQ, SU

August 1987

Wednesday, August 5	FD(a)
Monday, August 17	FD(b) Last day for filing tax return or obtaining additional 2 month extension by individuals who obtained an automatic 4 month extension
Friday, August 21	ST

September 1987

Thursday, September 3	FD(a)
Tuesday, September 15	FD(b), FC, FI/SI, SC Last day for filing tax return by corporations that obtained an automatic 6 month extension
Monday, September 21	ST

October 1987

Monday, October 5	FD(a)
Thursday, October 15	FD(b) Last day for filing tax return by individuals who obtained additional 2 month extension in August.
Wednesday, October 21	ST

November 1987

Monday, November 2	FQ, FU, FD(c), SQ, SU
Wednesday, November 4	FD(a)
Monday, November 16	FD(b)
Monday, November 23	ST

December 1987

Thursday, December 3	FD(a)
Tuesday, December 15	FD(b), FC, SC
Monday, December 21	ST

FD(a)	Last payment due on federal income and social security taxes withheld during the previous month if over $3,000 was withheld. You are required to deposit the amount withheld within 3 banking days after you reach $3,000 at the end of any eighth-monthly period (these periods end on the 3rd, 7th, 11th, 15th, 19th, 22nd, 25th, and last day of the month).
FD(b)	Federal income and social security taxes withheld must be deposited by this date if between $500 and $3,000 was withheld during the previous month. Earlier deposit is required when $3,000 is reached prior to this date.
FQ	Federal quarterly income and social security taxes withheld must be paid.
FU	Federal unemployment tax must be paid.
FC	Federal estimated corporation taxes must be paid if on calendar basis (note—fiscal year corporations pay this tax on 15th day of 4th, 6th, 9th, and 12th month of their year).
FI/SI	Federal and state estimated individual tax for previous quarter due.
FD(c)	Federal social security and withholding tax due on domestic workers.
ST	Maryland state sales tax due.
SQ	Maryland state income tax withheld due for previous quarter.
SU	Maryland state unemployment taxes due.
SC	Maryland state estimate of corporation tax due.

Prepared as a courtesy to Maryland Pharmaceutical Association Members, by C. W. Amos & Company, Certified Public Accountants with offices in Annapolis (269-1803), Bethesda (654-3044), Cambridge (228-7400), Salisbury (742-1328), and Baltimore (727-5341).

BIOTECHNOLOGY: WHAT IS IT? HOW IS IT DONE?

Biotechnology—the manipulation of a cell's genes so that it can produce new products—has catapulted science into a new era.

"We've made a quantum leap in our capabilities," says Ralph E. Christoffersen, Ph.D., vice president of biotechnology and basic research support for The Upjohn Company. "The sophisticated diagnostic tools, therapeutic agents and the methods for probing the nature of diseases through biotechnology will make much present medical technology and disease understanding seem primitive by comparison. And the advances we expect for agriculture and other industries should be equally spectacular."

The biotechnology revolution of the past decade stems from our ability to change the genetic information of cells and give them new properties. A cell can now be altered to synthesize antibiotics, chemicals, hormones, enzymes and scores of other compounds that might not otherwise be obtainable in useful quantities or at reasonable cost. Biotechnology can supply new diagnostic tools for the detection of diseases and still other tools for medical treatment. In addition, altering human genes may someday conceivably prevent certain genetic diseases. Moreover, biotechnology may produce a second "green revolution" by enabling plants to make their own fertilizers, a step toward expanding the world's food supply.

"The ultimate fruits of the labor (of biotechnology research) are not yet all that apparent," says Robert R. Gorman, Ph.D., director of cell biology at Upjohn. "They're limited only by the bounds of scientists' imaginations—rather than by money or resources."

Major types of biotechnology are highlighted below.

Hybridomas and Monoclonal Antibody Production

Antibodies are proteins that play a role in the immune system's defenses against disease. Antibodies are produced by short-lived, specialized cells known as *plasma cells*. These develop when B cells—a type of white blood cell—are stimulated by foreign invaders. Each variety of plasma cell produces a unique kind of antibody molecule.

Until recently, antibodies were produced commercially by immunizing animals (and sometimes people) with a foreign substance or microbe. The immune system responded by producing an array of antibody molecules derived from a larger number of stimulated B cells. A portion of blood was extracted and the fluid, containing a mixture of antibodies, was used for diagnosis or therapy.

Today, individual antibodies can be generated in sizable quantities by laboratory-grown *hybridomas*. These newly created cells are the result of joining an "immortal" cancer cell (one that will reproduce an unlimited number of generations), called a myeloma cell, and a stimulated B, or plasma, cell. (See figure 1.)

Two British scientists, Kohler and Milstein devised this technique in 1974 to produce various mouse hybridoma cells, each secreting a single type of pure antibody—*a monoclonal antibody*. This is their technique:

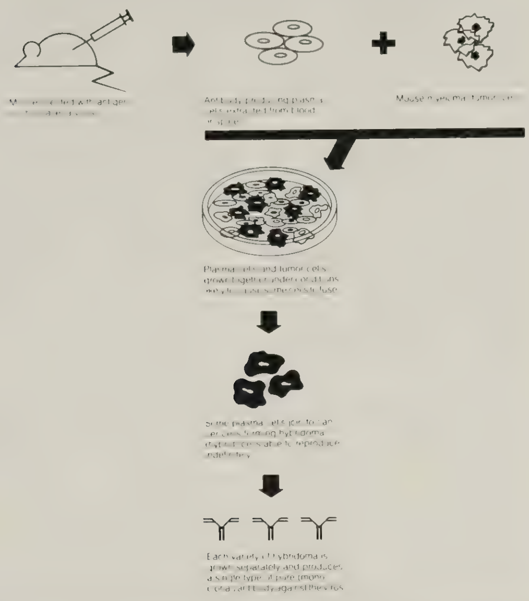
First, an animal is immunized with the foreign substance for which the antibody is desired. Its B cells are then obtained and mixed with myeloma cells under conditions that promote cell fusion. The resulting hybrid cells are grown individually. Those that are the product of the appropriate B cell and myeloma cell will secrete the desired antibody. The hybrid cell and its progeny can be grown indefinitely and the monoclonal antibody harvested repeatedly.

Monoclonal antibodies have many applications. They can be used to diagnose infections, to search out cancer cells and deliver drugs to them, and to detect and isolate body chemicals normally found in very small quantities.

In addition, a recent breakthrough paves the way for their use to fight disease. Robert C. Nowinski, Ph.D., affiliate professor of microbiology at the University of Washington School of Medicine in Seattle and president of Genetic Systems Corporation, has developed a technique to produce human monoclonals at concentrations 20 to 100 times greater than previously possible.

"We now have a practical method to make human antibodies for therapy," he says. These could be particularly useful in combating cancer and viral infections—realms where present medicines have met only limited success.

FIGURE 1 **HYBRIDOMAS PRODUCE VERSATILE MONOCLONAL ANTIBODIES**


Mouse myeloma tumor cells
Antibody-producing plasma cells extracted from blood
Plasma cells and tumor cells grown together under conditions [illegible] fuse
Some plasma cells join to tumor cells forming hybridoma [illegible] able to reproduce indefinitely
Each variety of hybridoma is grown separately and produces a single type of pure (monoclonal) antibody against the virus

[illegible]

Ann E. Berger, Ph.D., an Upjohn researcher in cell biology, is applying hybridoma technology to fuse human cancer cells and T cells. The latter are white blood cells that attack viruses and cancers. Yet relatively little is known about them. Dr. Berger is hoping to shed new light on normal T cell function as well as on their role in these disease states and possibly in arthritis and AIDS (acquired immune deficiency syndrome).

Recombinant DNA

Recombinant DNA (rDNA) refers to any DNA molecule with DNA sequences from two sources. The term currently is used to refer to blends made in a laboratory rather than those in nature. The blending process begins by cutting the two original DNA molecules with a *restriction enzyme* (a special type of biological catalyst). This produces DNA fragments whose ends fit together much the same way as two jigsaw puzzle pieces. The fragments from the two sources are mixed together under conditions that encourage them to adhere. Then another enzyme (called a ligase) chemically links the fragments. (See figure 2.)

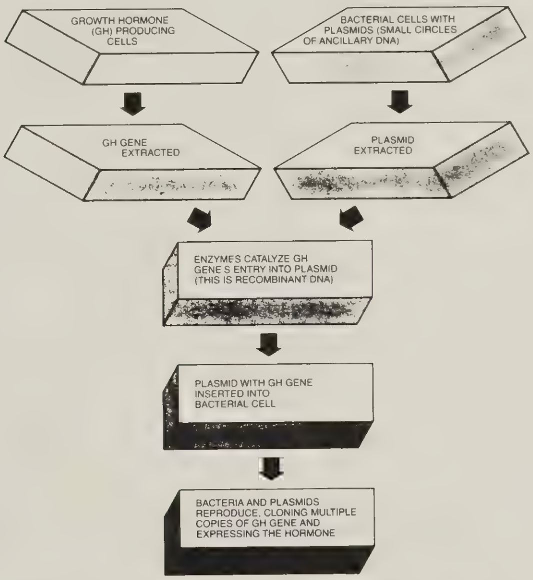
Thus far, recombinant bacteria are producing human insulin, growth hormone, interferons and other products. Additional medical, agricultural and industrial applications, too numerous to list, are in the works.

Cloned DNA

The process of cloning DNA refers to procedures that can result in production of millions of copies of a specific piece of DNA. The gene to be copied is first joined to the DNA of a *cloning vector* (an agent used to transfer genes from one cell type to another) by the method described above. The vector may be a *plasmid* —a small circular piece of DNA—that reproduces independently in the cell, generating hundreds of copies. (See figure 2.) Or it can be DNA from a *virus* that infects the cells. Both these cloning vectors have three important properties:

1. They contain instructions for multiplying independently of the host's chromosome(s).
2. They can enter specially treated cells.
3. They contain genes coding for a cell property that's easily detected so that scientists can readily determine which host cells have picked up the vector. For instance, scientists may give the vector genes that make cells resistant to a specific antibiotic. The host cells that have accepted the vector can then be isolated from other cells by growing them in the presence of the antibiotic.

FIGURE 2 **CREATING RECOMBINANT DNA AND CLONING IT— AND HOW BACTERIA CAN PRODUCE GROWTH HORMONE**


GROWTH HORMONE (GH) PRODUCING CELLS
BACTERIAL CELLS WITH PLASMIDS (SMALL CIRCLES OF ANCILLARY DNA)
GH GENE EXTRACTED
PLASMID EXTRACTED
ENZYMES CATALYZE GH GENE'S ENTRY INTO PLASMID (THIS IS RECOMBINANT DNA)
PLASMID WITH GH GENE INSERTED INTO BACTERIAL CELL
BACTERIA AND PLASMIDS REPRODUCE, CLONING MULTIPLE COPIES OF GH GENE AND EXPRESSING THE HORMONE

The above example shows that by creating recombinant DNA, a particular gene can be cloned (useful in itself for further study of genetic diseases) and/or its product manufactured by bacterial cells. Until the development of this technology, growth hormone was not available in adequate amounts. Formerly, it was extracted from animal glands and was extraordinarily expensive.

Once a segment of DNA is cloned in sufficient quantities, its structure can be analyzed and its functions more readily studied. Scientists at the National Institutes of Health in Bethesda, Md., recently succeeded in cloning genes responsible for various forms of Gaucher's disease—a defect in fat storage that can impair the nervous system and other organs, at times producing disability and even death.

"Now that we've identified the defective genes involved," says Edward I. Ginns, M.D., Ph.D., a neurologist on the NIH research team, "the next step is to use the gene from normal people to produce normal protein—the one Gaucher's victims lack. We'll insert this gene into bacteria where we can make enough protein to learn more about it. Perhaps 5 to 10 years from now, we'll be ready to try gene therapy—inserting the gene into patient's white blood cells. We're hoping that in children the cells will then reproduce at appropriate sites around the body and generate enough of the protein to prevent major problems."

Gene Transfer Techniques

Every species of animal, plant and bacterium jealously guards its genetic integrity. Thus, special tricks are necessary to get "foreign" DNA into a cell, to keep it from being chewed up by the cell's enzymes, and to get the cell to read the genes and follow their instructions.

The most foolproof method is to splice the gene onto a plasmid that normally is found in the host cell. Plasmids are present in a wide variety of cells, especially those of bacteria and yeast. Other plasmid-like genetic elements, called *transposons,* exist in some higher plants and animals as well as in bacteria and yeast. They have the remarkable ability to move around from one piece of genetic material—*chromosome*—to another, inserting their genes wherever they move. Geneticist Barbara McClintock, Ph.D., of Cold Spring Harbor Laboratory in Long Island, N.Y., discovered transposons in 1941 while studying the genetics of maize. Some 40 years passed before the full importance of her work was recognized. In 1983, Dr. McClintock was awarded the Nobel Prize for Physiology or Medicine.

Transposons have also been isolated from fruit flies. These transposons have been used as cloning vectors to transfer genes from one fruit fly to another.

Some viruses native to mammalian and bacterial cells behave much the same way as transposons. That is, they infect the cell and insert their genes into the chromosome. Mammalian cells have been engineered using the DNA of such viruses as vectors.

Finally, genes can be introduced into the cells of animals by injecting them with a very fine needle under a microscope. This technique doesn't always result in stable integration of the foreign gene into the host's chromosome. Sometimes the transferred gene is lost when the host cell divides. Human genes have been successfully introduced into fertilized mouse eggs. The mouse followed the genetic instructions and also passed the gene to its offspring. The gene for human growth hormone was transferred to mice that eventually grew to be larger than their untreated litter mates.

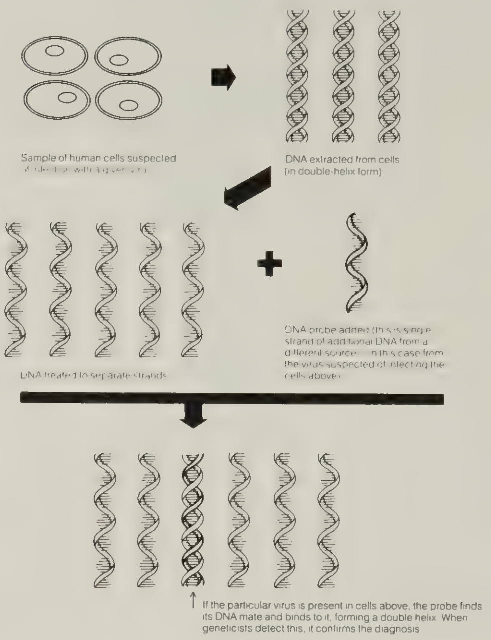
Gene transfer techniques must be perfected before scientists can hope to perform successful gene therapy on human patients with hereditary diseases.

DNA Probes

A major goal of recombinant DNA technology is to isolate and purify single, specific genes. Once this is accomplished, such a gene can be used:

1. In its single-stranded form, as a *DNA probe* to "fish" for its mate in a *DNA library* (a collection of DNA pieces that result from chemically "chopping up" the DNA of a given type of cell). If, for example, a cell or group of cells is suspected of harboring a herpes infection, one can use a DNA probe from that virus to fish in the DNA library cloned from the cells. This is a very sensitive way to test for the presence of herpes DNA and, hence, for the infection. The DNA probe will bind to its mate—the complementary strand with which it forms a double helix—if herpes DNA is present. (Figure 3 illustrates this technique.) It can be recognized and retrieved by labelling it with radioactivity or other methods.

FIGURE 3 **HOW BIOTECHNOLOGY CAN DIAGNOSE A SUSPECTED VIRUS INFECTION**

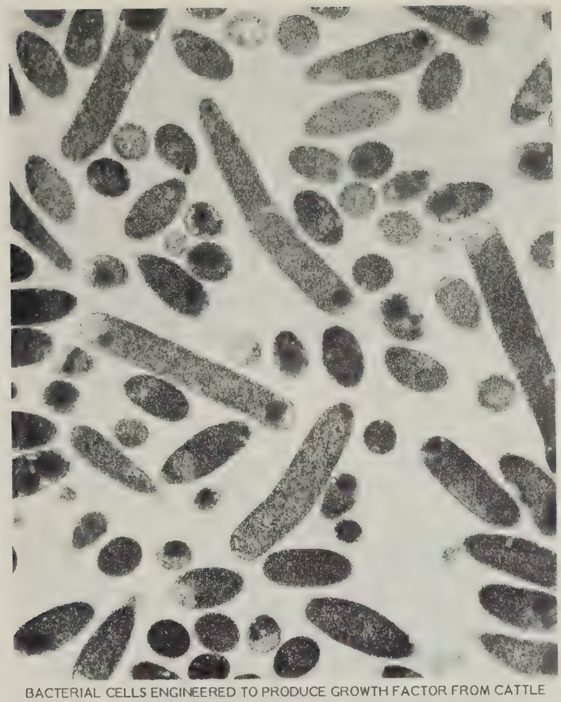

Sample of human cells suspected of infection with a given virus
DNA extracted from cells (in double-helix form)
DNA treated to separate strands
DNA probe added (this is single strand of additional DNA from a different source — in this case from the virus suspected of infecting the cells above)
If the particular virus is present in cells above, the probe finds its DNA mate and binds to it, forming a double helix. When geneticists detect this, it confirms the diagnosis

This same procedure—using different probes—may one day be used to identify any virus or locate any gene be it normal or abnormal in human cells

2. To synthesize a desired chemical. If a full gene is identified that codes for a sought-after protein, it can be inserted (by means of techniques previously described) into microbial cells. These are grown in vast numbers and used to produce the particular protein.
3. To ascertain on which chromosome a particular gene is located. In complex organisms such as humans, this has allowed scientists to begin mapping all 46 human chromosomes. Eventually, they'll be able to detect chromosomal abnormalities, genetic diseases and the presence of viruses and cancer genes in the cell, among other applications.

Researchers at the National Cancer Institute envision a day in the near future when an individual's entire gene pool can be analyzed. A "total gene screen" could reveal dormant vulnerabilities. Such a futuristic blood test could reduce unforseen health risks by alerting individuals to potential problems before they develop.

In order to find a particular whole gene, scientists must often go back a step further. If they know part of



BACTERIAL CELLS ENGINEERED TO PRODUCE GROWTH FACTOR FROM CATTLE

The E. Coli cells shown above -- magnified 21,000 times -- are genetically engineered to produce BST, bovine somatotropin (see dark spots within cells) a growth factor found in cattle. Photograph: The Upjohn Company.

the structure of the protein product, they can use this information to construct an *oligonucleotide*—a fragment of the desired gene. This can be carried out using an automated DNA synthesizer dubbed a "gene machine." They then utilize the newly made piece of DNA as a probe to pull the full gene out of the appropriate DNA library.

Diagnosis of genetic diseases such as Huntington's chorea (a degenerative disease of the nervous system) works much the same way as detecting a virus. Geneticists would prepare a single-stranded piece of the usually double-stranded DNA associated with the Huntington's gene (the latter itself has not yet been identified). They use this as chemical bait to fish for its mate in a preparation of single-stranded DNA fragments from cells of a patient suspected of having the disease. If the mate is present, it will bind to the probe, forming a DNA double-helix and confirming the presence of the Huntington's gene.

"At present, the individual's entire family must be screened for the presence of the abnormal gene," says Haig Kazazian, M.D., professor of pediatrics at the Johns Hopkins University School of Medicine in Baltimore, Md. "This complex task determines whether the abnormal gene was inherited and whether or not the gene will be expressed—that is, actually cause the disease."

Genetic screening in families at risk for Huntington's disease is now under way at Johns Hopkins. Dr. Kazazian reports that such gene anaylsis has a 5 precent margin of error.

Protein Engineering

What is protein engineering, and why is it important?

In addition to serving as cells' structural building blocks, proteins make up cells' enzymes, the catalysts responsible for all the cells' activities.

The aim of protein engineering is to alter the DNA of organisms so that they will produce large quantities of easily isolated, heat-stable enzymes for a wide variety of uses.

Industry uses millions of dollars' worth of enzymes each year to produce valuable chemicals. For example, the enzyme alpha-amylase is used to produce sugars from starch; the enzyme cellulase is used to convert waste paper or other waste cellulose into sugar or liquid fuel.

Although an enzyme may be very efficient within a cell, it may not lend itself to industrial-scale production. The enzyme may not, for example, be released from the cell that naturally produces it, or once secreted, the enzyme may break down. It also may be produced naturally in quantities adequate for the needs of the cell, but not in quantities large enough to economically harvest or concentrate.

In nature, the DNA-protein-enzyme connection works like this: Enzymes are made of proteins, which are composed of amino acids. DNA serves as a template for the formation of RNA. RNA serves as a template in protein synthesis—stringing together amino acids in the proper order and chain length.

The sequence of amino acids strung together in the protein and enzyme determines the enzyme's properties; how fast it works, how stable it is, how much is produced by the cell and on which molecules the enzyme acts.

In industry, scientists are using several approaches to produce large quantities of desired enzymes and to shorten the amount of time required to develop new therapeutic agents.

The most direct approach is to isolate cells that synthesizes the desired enzyme, then clone the gene for the enzyme in a bacterium or yeast.

Other approaches involve protein engineering and the production of new proteins that didn't exist before. One example is the slight modification of a gene to redesign the enzyme it produces. A minor modification in the amino acid sequence may enhance the protein's stability or catalytic properties.

In another example, if major changes are required, it may be necessary to synthesize an entire gene in the laboratory and then insert it into a host cell using a cloning vector. Synthesis of a functional gene has been achieved for insulin, human growth hormone and interferon. All have been cloned in bacteria that now have the capacity to produce these important therapeutic agents.

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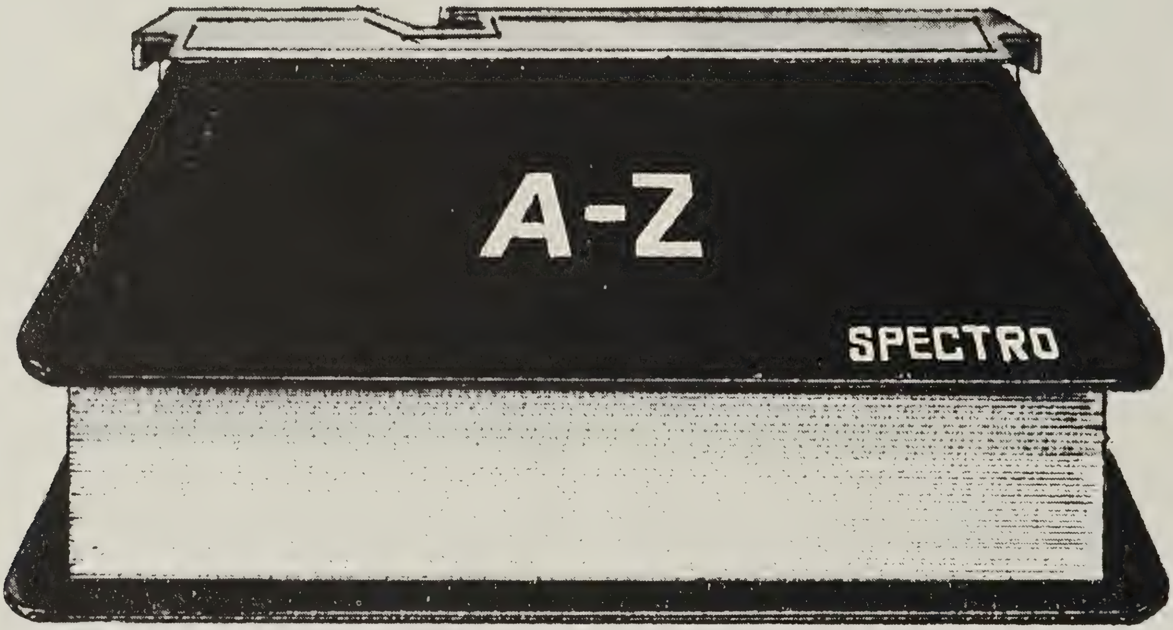

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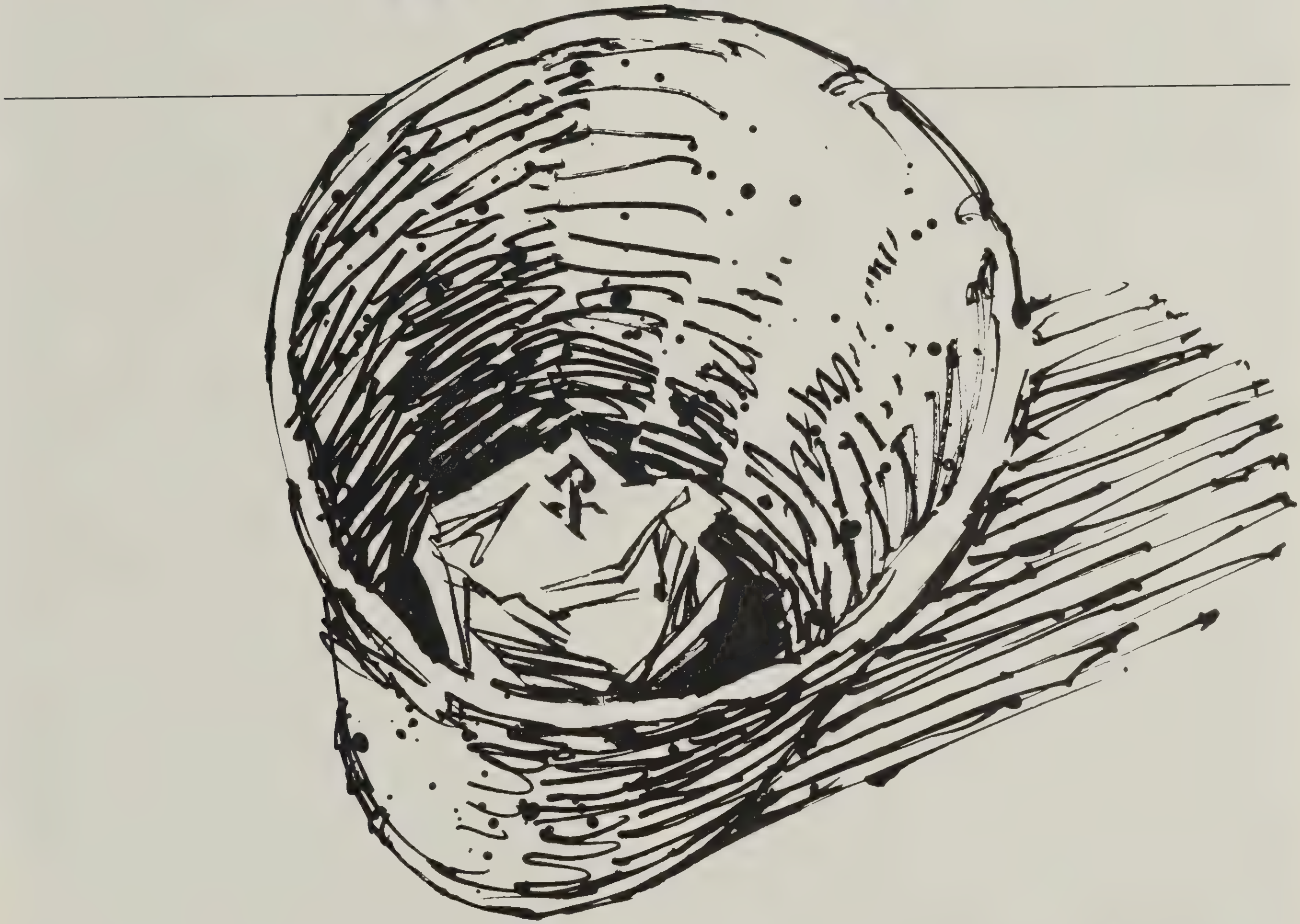

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Another 6% told tales of prescriptions lost, prescriptions forgotten… or drugs that weren't available.

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*According to the 1985 National Prescription Buyer Survey by Market Facts, Inc.

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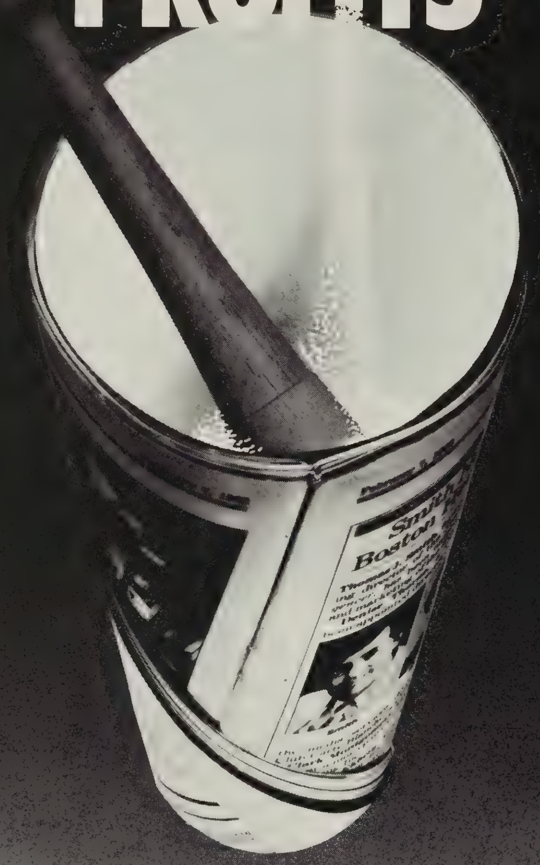

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MPhA Board Chairman, Madeline Feinberg (left) Chaired a meeting at the American Gerontological Society in Chicago, Illinois. Pharmacists from throughout the country studied the issue of establishing a Special Interest Group within the Society for Pharmacy.

The faculty from the November 9th Continuing Education Coordinating Council's program on the Role of Pharmacist in Cancer Prevention is shown. They are: (Left to right) Barbara Conley, Suzanne Cronquist, Teresa J. Melink and Rebecca Finley, who was program Moderator.

Pharmacist Robert E. Proudfoot from Oakland Maryland, was the MPhA Bowl of Hygeia Award recipient this year for his work in community public service. He was honored by the A. H. Robins Co.

John H. Kennedy has been appointed to serve as the Chief Executive Officer by the Board of Directors of Alco Health Services Corporation.

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The Compounders Corner

by Loyd V. Allen, Jr., Ph.D., and M. Lou Stiles, M.S.
The University of Oklahoma College of Pharmacy, Oklahoma City, Oklahoma 73190

DECUBITIS MIXTURE:

Rx	Betadine Ointment	1 oz
	Betadine Solution	1 oz
	Sucrose	2 oz

PREPARATION:

Dissolve the Betadine Ointment in the Betadine Solution.
Add the Sucrose with stirring until the product is uniform.

USE:

Treatment of decubitus ulcers.

PACKAGING:

Air-tight containers, either plastic or glass.

LABELING:

Keep tightly closed, for external use only.

STABILITY:

This preparation should be kept tightly closed in a cool place to avoid loss of iodine.

DISCUSSION:

Betadine Ointment consists of 10% povidone-iodine in a water-soluble polyethylene glycol ointment base.

Betadine Solution is a mahogany colored aqueous solution of 10% povidone-iodine (1% available iodine) plus a surfactant. Both products are miscible with water and alcohol. The ointment is used for the prevention of infection in burns, cuts, abrasions, poison ivy and insect bites as well as for the treatment of infections in varicose and decubitis ulcers. The solution is the microbicide of choice for disinfection of wounds and for the treatment of lacerations, abrasions, and first through third degree burns.

Incompatibilities of these two products include hydrogen peroxide (where oxygen is released resulting in a pressure buildup in the container) and Lavacol/Parke-Davis (where acetone and ketone in the Lavacol result in free iodine being lost). The activity of Betadine products can be decreased by alkalais.

Sucrose is a colorless, odorless crystal or powder with a sweet taste. It is freely soluble in water, alcohol, and freely soluble in 70% alcohol. Sucrose is stable in the dry state but subject to (1) microbial contamination in aqueous solutions, (2) degradation by heating, and (3) hydrolysis in acidic solutions. It is widely used as a sweetening agent, demulcent and as a pharmaceutical vehicle in the form of syrup. In the present prescription, sucrose evidently exerts some beneficial effect, possibly bactericidal, through the mechanism of a hyperosmotic environment. Sucrose is also used for decubitis ulcers in a Carbopol vehicle, as will be described in a separate article.

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The authors make no claims concerning the therapeutic efficacy of the products or preparations discussed in this series. These articles are intended to be a forum for extemporaneously prepared nonsterile and sterile prescriptions currently being compounded throughout the United States.

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The St. Francis Mobile Dental Service is making Dental House Calls for the Homebound patients in Baltimore. To make a referral or learn more information call: 235-8686 or 728-3500.

The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

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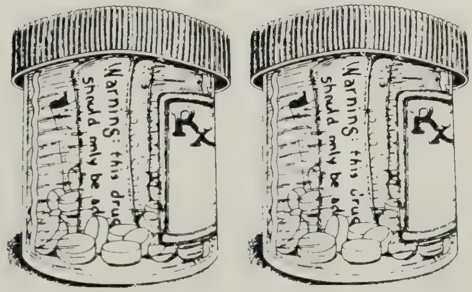
Warning: this drug should only be ad
Rx
Warning: this drug should only be ad
Rx

calendar

Jan 14–22—MPhA Trip to Hawaii
Jan 16–18—MPhA/Alumni Ski Weekend at Hunter Mountain
Jan 29—MPhA Board of Trustee Meeting
Feb 8—MPhA Mid-year Meeting, Annapolis Hilton
Feb 16–24—Alumni/School annual giving Phonothon
March 8—BMPA Annual Dinner Dance.
March 15–21—National Poison Prevention Week
Apr 30—(Thurs) Seminar: Chronic Care & The Elderly: An Update-Hilton Reisterstown Road
May 17—CECC Seminar on Arthritis
May 21—(Thurs) Alumni Association annual Graduation Banquet

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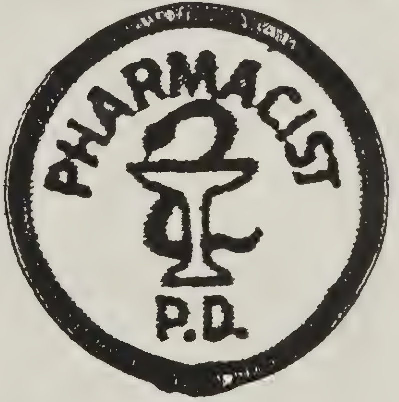

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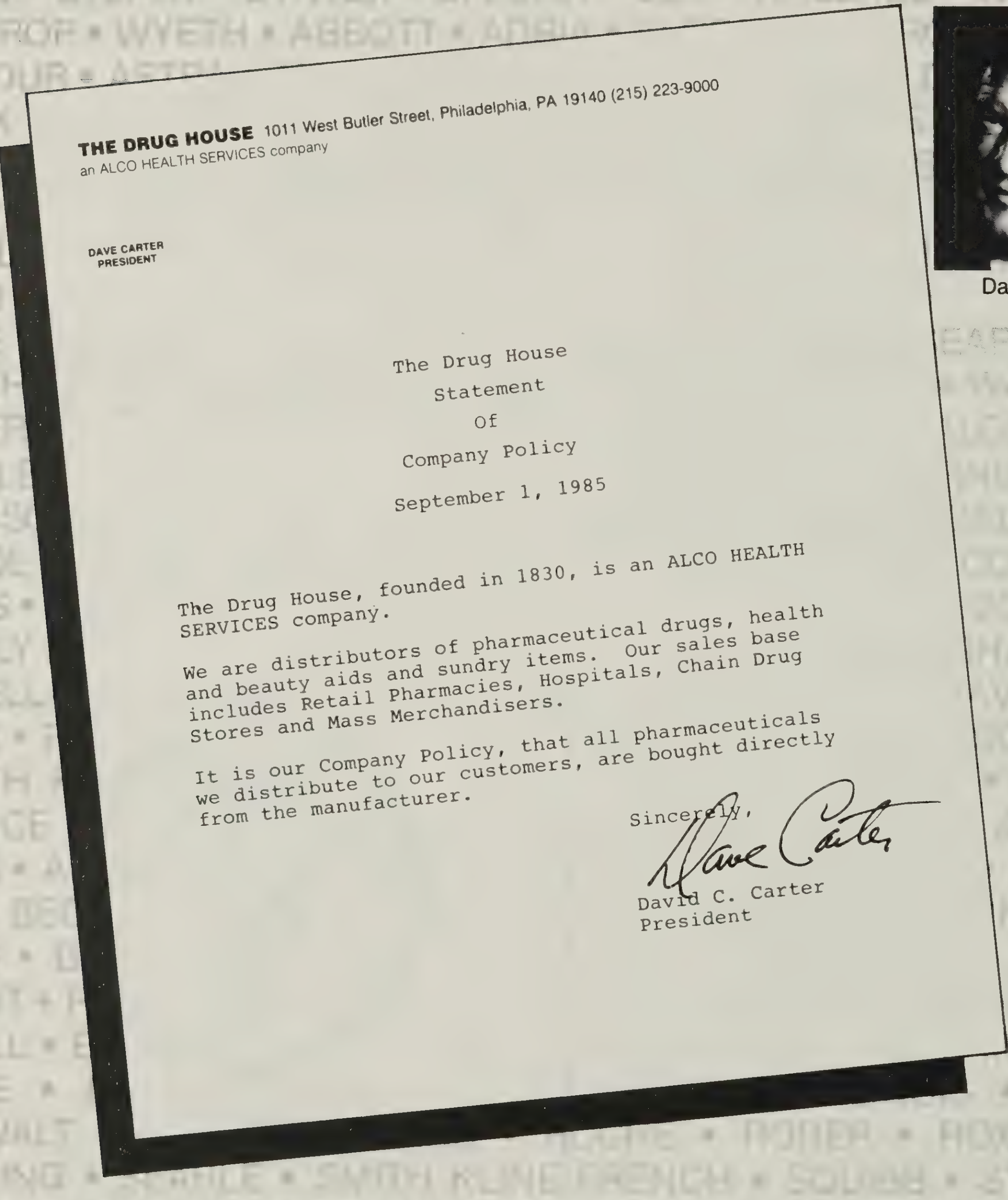

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THE MARYLAND PHARMACIST

Official Journal of
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Advising Consumers on Alcohol and Food Overindulgence

— Thomas A. Gossel
— J. Richard Wuest

Winning Against Mail-Order

— Jim Dickinson

Cancer: New Techniques in Early Diagnosis

Tips for Easing the Strain of Standing

Timely Topics: Alzheimer's Disease, Part II

— Peter P. Lamy
— Ilene H. Zuckerman

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
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FEBRUARY, 1987 VOL. 63 NO. 2

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I sure hope so, at least this time. If you've come this far, please continue. Following are some serious issues affecting the future of our profession:

Dispensing Physicians: Last year, our major accomplishment was Senate Bill 830, which would regulate physicians selling medicines to their patients. Now the Federal Trade Commission has urged Maryland regulators to encourage doctors to sell prescription drugs directly to their patients. Are we right back where we started?

Dispensing HMO's: Word has it that technicians in HMO's are dispensing prescription medicines in ever-increasing numbers. Isn't this only supposed to be handled by a physician or a pharmacist?

Discriminatory Pricing: About three years ago, the aforementioned Federal Trade Commission wrote me that they had instructed their staff to study "the issue of competition between private firms and tax-subsidized nonprofit institutions, and the extent to which the tax-exempt status of the latter may confer an anticompetitive advantage." No doubt, the FTC's time and energy has been drained by deciding that physicians should sell medicines and could not possibly be expected to look into discriminatory pricing violations in a short span of only three years.

These are only three of the issues that a handful of pharmacists are wrestling with. If anyone's out there that can give us guidance or advice on how to solve these and other problems, *PLEASE CONTACT US*. We're open to suggestions and we are asking for your help.

George C. Voxakis
PRESIDENT

CONTINUING EDUCATION FOR PHARMACISTS

VOL. IV, NO. 1

Advising Consumers on OTC Products for Overindulgence in Alcohol and Food/ Alcohol Combinations

by Thomas A. Gossel, R.Ph., Ph.D.
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and

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Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss symptoms of overindulgence in alcohol or food/alcohol combinations;
2. present OTC products that are safe and effective for treating symptoms of overindulgence;
3. give some background information on remedies purported to prevent inebriation.

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Objectives

At the conclusion of this lesson, the successful participant will be able to:

1. differentiate between overindulgence in alcohol and overindulgence from food/alcohol combinations from the symptoms described;
2. state which OTC product ingredients have been shown to be safe and effective for treatment of overindulgence symptoms;
3. cite the reason why certain warning statements must be included on labels of OTC products for overindulgence;
4. cite the reasons why there are currently no OTC products to prevent inebriation; and
5. provide appropriate patient advice to pass on to consumers purchasing OTC products for treatment of symptoms of overindulgence.

The quantity of alcoholic beverages Americans consume has been estimated to be three gallons per person each year. This calculation computes to approximately one ounce of absolute (100 percent) alcohol per person per day.

Psychological and physiological consequences of chronic alcohol ingestion are devastating when one considers the organ degeneration, lost careers, and broken homes. There is no OTC product that will alleviate or minimize the occurrence of the effects of chronic alcoholism.

There is one effect of periodic overindulgence that most persons who consume alcoholic beverages have encountered at least once, and many have experienced on numerous occasions! This is the syndrome of events that often follows overindulgence, i.e., the hangover.

Hangover

The term *hangover* describes a cluster or series of symptoms that occur several hours after ingestion of a "large" quantity of alcohol. *Large* is defined as an amount in excess of that which an individual can tolerate, and his system can metabolize without difficulty.

As defined by FDA, hangover is "a condition consisting of a complex of symptoms involving the gastrointestinal, neurologic, and metabolic systems that follows recent acute ingestion. The symptoms may include nausea, heartburn, thirst, tremor, disturbances of equilibrium, fatigue, generalized aches and pains, headache, dullness and/or depression or irritability."

A complete profile of symptoms is listed in Table 1. Hangover is not the same as alcoholism, which refers to chronic alcohol ingestion with resultant organ pathology.

Symptoms of hangover involve a number of bodily functions. As stated above, they generally appear several hours after moderate alcohol intake and are most commonly experienced after awakening from an excessive alcoholic beverage intake. The slang expression that described this is, "the morning after the night before!"

A number of studies with volunteers, and results of numerous surveys have defined symptoms of overindulgence in alcohol, as well as overindulgence from a combination of food and alcohol.

Symptoms fall into four categories or clusters: heartburn, fullness, nausea, and associated nervous problems. It is of some interest that the FDA/OTC advisory panel which looked at the data concluded that there is a significant target population for whom overindulgence is accompanied by a symptom reported as upset stomach.

TABLE 1

Symptoms of Hangover

I. Those Seen Commonly

- Depression
- Disturbed balance
- Dullness
- Fatigue
- Headache
- Heartburn
- Irritability
- Muscle aches
- Nausea
- Thirst
- Tremors

II. Those Seen Occasionally

- Anxiety
- Backache
- Bad breath
- Belching
- Burning eyes
- Confusion
- Constipation
- Diarrhea
- Dizziness
- Dry mouth
- Faintness
- Flushed feeling
- Giddiness
- Hunger
- Insomnia
- Lassitude
- Loss of appetite
- Loss of taste
- Malaise
- Melancholy
- Muscle weakness
- Nasal discharge
- Nervousness
- Nystagmus
- Pale skin
- Palpitations
- Perspiration
- Respiratory difficulties
- Runny nose
- Shaking
- Shortness of breath
- Sleeplessness
- Sluggishness
- Stomach ache
- Sweating
- Tension
- Tinnitis
- Tiredness
- Vomiting

Another relatively interesting point is that the panel could not find an identifiable single OTC drug product ingredient that relieved all of these symptoms.

Home Remedies

Through the years, a number of home "cures" have been advocated to treat overindulgence and hangover. These included exotic remedies such as owl's eyes and eggs, raw or cooked fish, ashes from various woods, myrrh, wearing a garland of celery or parsley around the neck, rolling naked in the snow, basking in saunas, and sniffing pure oxygen.

Even drinking additional alcohol has been tried following the notion of "taking a hair of the dog that bit you!" Alcoholic-based beverages such as the Bloody Mary, Singapore Sling, and Suffering Bastard reportedly were originated to reduce the intensity of the symptoms of hangover. Research to date has failed to show that alcohol cures or minimizes symptoms of overindulgence or hangover.

OTC Remedies

Americans have self-medicated themselves for overindulgence and hangover for years with OTC products such as Alka-Seltzer (aspirin, sodium citrate), Bromo Seltzer (acetaminophen, sodium citrate), and Pepto Bismol (bismuth subsalicylate). Ingredients in these products are concluded to be safe and effective analgesics (e.g., aspirin and acetaminophen) or antidiarrheals (e.g., sodium subsalicylate).

When the panel reviewed the evidence for these agents to treat symptom clusters, it found much confusion and overlap as far as hangover and overindulgence. *Overindulgence* in food/alcohol combinations normally produces symptoms of upset stomach (primarily heartburn, fullness and nausea) that appear within an hour of consumption and persist up to 24 hours. Symptoms of *hangover*, on the other hand, generally do not appear for several hours to a day.

The panel noted that many of these same symptoms are also produced by other, more serious causes. The conditions may be indistinguishable from each other. For example, nausea may occur in conditions such as uremia, ketoacidosis, hypercalcemia, cerebral edema, peptic ulcer, and cancer. It may be associated with pregnancy, motion sickness, stress, headache, and fright. Heartburn may result from gastric hyperacidity, acute hyperemia or gastritis.

Since these responses are presumably caused by different mechanisms, a product intended to treat symptoms resulting from one cause may not effectively treat similar ones resulting from a different cause.

Therefore, the panel separated the conditions for which these OTC drug products might be used into three distinguishable categories:

1. relief of upset stomach due to overindulgence in food/alcohol;

2. relief of hangover symptoms; and

3. prevention of inebriation.

There was a fourth potential category, prevention of hangover. The panel could find no evidence that any drug would prevent this. Results of the advisory panel's deliberations on the above three categories are presented in Table 2.

TABLE 2

OTC Drug Products for Relief of Symptoms of Overindulgence

1. **Upset stomach due to overindulgence in food/alcohol combinations**
   - Acetaminophen/sodium citrate
   - Aspirin/sodium citrate
   - Bismuth subsalicylate
2. **Hangover** (drugs used in combination)
   - Analgesics
   - Antacids
   - Stimulants
3. **Prevention of inebriation**
   - Activated charcoal*
   - Fructose*

*Some, but inconclusive evidence of efficacy

The conclusion on combinations of ingredients is somewhat unusual. The panel recommended that combinations are therapeutically better than single ingredient products.

This belief resulted primarily from the clinical experience of panel members. Their view was that people have traditionally found it convenient to treat hangover symptoms with an analgesic for headache, antacid for upset stomach, and caffeine for fatigue or dullness.

Since other advisory panels had reviewed the previous three drug groups and reported on their effectiveness for the respective symptoms, this particular panel waived the need for clinical studies to document safety and effectiveness of the appropriate combinations as long as they met all the other criteria for Category I status. These criteria included proper labeling and documentation to show that all ingredients add to the total therapeutic activity claimed by the manufacturer. Table 3 lists OTC combination drug products cited as effective in relieving hangover symptoms.

OTC's With Proven Effectiveness

Bismuth Subsalicylate. In 1975, the advisory panel that reviewed OTC gastrointestinal drugs found **bismuth subsalicylate** (active ingredient in Pepto Bismol) to be an effective antidiarrheal in doses of 0.5 to 2 grams taken three to four times daily.

TABLE 3

OTC Combination Product Ingredients for Relief of Hangover

- Aspirin, citric acid, sodium bicarbonate (in solution)
- Acetaminophen, citric acid, sodium bicarbonate (in solution)
- Aspirin, caffeine, aluminum hydroxide, magnesium carbonate
- Acetaminophen, aspirin, caffeine, magnesium trisilicate, magnesium carbonate, and aluminum hydroxide gel

This particular panel also evaluated the ingredient for treating symptoms of overindulgence in food and alcohol. It reported that doses of 325 mg taken up to 8 times daily at intervals of 0.5 to 1 hour (maximum of 4.2 grams/day) are safe and effective for this purpose.

There were some safety concerns regarding bismuth subsalicylate. But the panel rejected their importance stating that the concerns related to different bismuth salts, or subjects taking doses significantly greater than 4.2 grams daily.

One potential toxic action related to bismuth subsalicylate is the possibility of salicylate overdose in persons who take high doses of aspirin concomitantly. In a test that measured salicylate levels following ingestion of Pepto Bismol in recommended doses, an average blood level of 13.7 mg/100 ml was recorded. This was less than the minimum salicylate level (20 mg/100 ml) at which tinnitus (usually the first symptom of aspirin toxicity) appears.

The panel reported that symptoms of overindulgence in alcohol and food represent a temporary condition that only requires short-term treatment. There is little danger involved, but the potential for toxicity nevertheless exists. Therefore, it recommended that the following warning be placed on the label of products containing bismuth subsalicylate: "*This product contains salicylate. If taken with other salicylate-containing preparations, such as aspirin, and ringing in the ears occurs, discontinue use. If taking oral medication for anticoagulation (thinning of the blood), consult a physician before taking this product.*"

The warning about not taking the product if the patient is taking an anticoagulant relates to a potential drug interaction between salicylate and warfarin (Coumadin®). Salicylate displaces warfarin from its albumin binding sites, possesses intrinsic hypoprothrombinemic effects (reduced formation of prothrombin), and in acetylated forms (i.e., aspirin) inhibits platelet adhesiveness and aggregation.

All these can decrease clotting mechanisms. Each action is additive to the action of warfarin, and serious bleeding episodes may occur in susceptible individuals. Concurrent use of these agents is not an absolute contraindication but for patient safety, it is best not to self-medicate with salicylates without consulting a physician.

Sodium Citrate. The second drug found to be safe and effective for OTC use in relieving symptoms of upset stomach due to overindulgence in a food/alcohol combination is sodium citrate in solution. OTC products can be marketed as effervescent tablets or granules that are dissolved before ingesting. The citric acid and sodium bicarbonate that comprise the effervescent product are placed in water to release the active ingredients: sodium citrate along with carbon dioxide (the fizz) and other chemicals.

The total daily dose recommended by the advisory panel for persons under age 60 is 17.2 grams, taken in divided doses. The total daily dose for patients over 60 is one-half this, or 8.6 grams. This reduced dosage is necessary because geriatric patients are more likely to experience difficulty excreting sodium from the kidney than their younger counterparts.

Two warnings are required on the labels of sodium citrate solution products. The first is, "*If you are 60 years of age or older, the maximum daily dose should not exceed ____ of this drug.*" (The space is to be filled in with the total number of dosage units that comprise the 100 mEq.). The second is "*If you are on a sodium-free diet, do not take this product except under the supervision of a physician.*"

The first warns about the total daily limit. The other advises consulting a physician before using the product if the purchaser is on a salt-free diet. This latter warning is suggested because the total doses are 200 mEq and 100 mEq respectively, which is too much sodium for a person on a low-salt diet.

Because pain and/or headache often accompany nausea, heartburn and fullness of hangover and overindulgence, sodium citrate combined with aspirin (e.g., Alka-Seltzer) or acetaminophen (e.g., Bromo Seltzer) have been found to be safe and effective OTC combination ingredients. Again, these must be available in a dosage form that will be taken as a liquid rather than as a tablet or capsule.

The above findings led to a point of controversy. There are some experts who believe that these aspirin/antacid combinations are potentially dangerous to persons who already have gastric upset, because aspirin causes increased gastrointestinal blood loss.

This particular panel and FDA concluded that the gastric erosion caused by aspirin occurs as it crosses the stomach's mucosal cells on its way into the blood. In the presence of a strong buffer (such as sodium citrate), aspirin is converted to sodium acetylsalicylate which is not absorbed by the cells of the gastric mucosa in significant amounts which cause gastric damage.

The panel continued by stating that clinical studies have yet to show significant blood loss, gastric erosion or damage to stomach tissue. It recommended a Category I status for the combination.

The labeling of combination products containing acetaminophen, antacids, salicylates or stimulants must contain appropriate cautionary statements for each ingredient. Those that relate to salicylates are: "*If symptoms persist, or new ones occur, consult your doctor*"; "*Stop taking this product if ringing in the ears occurs*"; "*If taking medication for an anticoagulation (thinning of the blood) effect, consult a doctor before taking this drug;*" and "*Do not take this product if you are allergic to salicylates such as aspirin.*"

For products containing acetaminophen, the recommended warnings are, "*If symptoms persist or new ones occur, consult your physician;*" and "*For occasional use only.*"

Can Inebriation be Prevented?

Two substances have been promoted for preventing inebriation. These are activated charcoal and fructose. As far as FDA is concerned, both are safe, but neither has yet been proven effective for this indication.

Activated Charcoal. Activated charcoal adsorbs congeners in alcohol *in vitro*. All alcoholic beverages contain congeners, a term meaning "of the same kind." Essentially, congeners provide the characteristic odor, color and taste of the individual beverages. The term *fusel oil* is often used to describe them but this is technically incorrect since fusel oil is officially the oily residue left behind after ethanol is removed from a distillation process.

Alcohol congener content and concentration vary among different beverages, and more than 400 compounds have been identified in various alcoholic drinks. These include acetaldehyde, ethyl formate, ethyl acetate, methanol, n-propanol, butanol, and amyl alcohol.

There is convincing evidence that it is the congeners of alcohol that cause the symptoms of hangover. There is also a strong feeling that they contribute to the overall development of intoxication. For example, one study found a higher incidence of severe hangover in subjects drinking bourbon (greater congener content) than in those ingesting vodka (lower congener content). And when the various congeners are ingested alone, they all produce symptoms identical to those experienced in hangover.

Activated charcoal is safe in antidotal doses up to 120 grams. Its adsorptive action on alcohol *per se* is limited to 300 to 400 mg ethanol per gram activated charcoal *in vitro*. Whether or not significant clinical benefit results with activated charcoal in modifying inebriation has not been shown.

Fructose. Fructose (levulose, fruit sugar) is claimed to prevent alcoholic intoxication. It is safe in oral doses up to 150 gm/day. Fructose is rapidly removed from the blood so it does not affect blood sugar levels, and it does not require insulin for its movement across cellular membranes.

Fructose action on blood alcohol levels has been of interest for almost 50 years. While some clinical studies have assessed fructose response on lowering blood alcohol levels, there are no studies that specifically support its role in preventing inebriation. It has been given orally and intravenously before, during, and after ethanol ingestion. Some authorities report that fructose can enhance elimination of alcohol, most likely by increasing its rate of metabolism. Others dispute this claim and state that any effect it might have on lowering blood alcohol levels is insignificant.

FDA stated its concern that products claimed to minimize or prevent inebriation may actually present a potential health threat. One national group concerned with highway safety reports that each year about 25,000 automotive deaths and thousands more serious disabilities are due to intoxicated drivers. Such products may impart a false sense of security to persons consuming alcoholic beverages. They drive when they should not and the end result could indeed be disastrous to the drivers and to innocent victims.

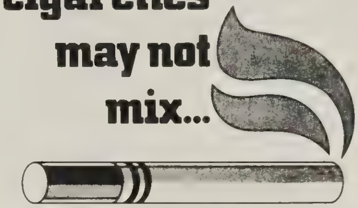
Nevertheless, manufacturers have been encouraged to pursue studies to ascertain whether or not activated charcoal and fructose are effective for their claimed indications. At the time of publication of this article, these studies were not in progress.

Consumer Advice

The best advice for treating symptoms of overindulgence and hangover is to not imbibe in the first place! Since this advice is unlikely to be heeded, there are several OTC products that have been found to be effective for the resulting upset stomach and hangover. They include Alka-Seltzer, Bromo Seltzer, and Pepto Bismol.

Taken as directed, these products pose no problems to most individuals. However, people with special medical problems (e.g., those with aspirin sensitivity, patients taking anticoagulants and persons on low-salt diets) should carefully read the product labeling to assure that it will not aggravate their conditions.

Geriatric individuals should be reminded that their dosage is less than that of younger persons. They should also inform their physicians that they are taking these products.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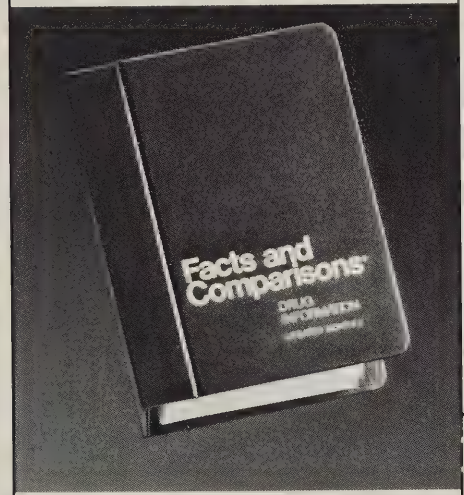

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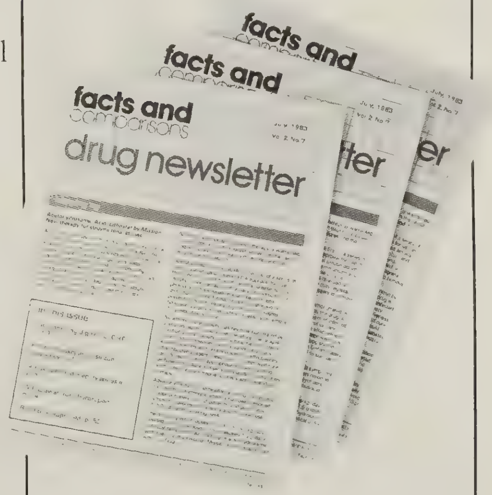

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"TIMELY TOPICS"

A regular monthly feature sponsored by the Parke-Davis Center for the Education of the Elderly and the Elder-Health Program, University of Maryland School of Pharmacy. At the conclusion of each series, a sample "Elder-Ed" talk for presentation to the community will be outlined.

PHARMACOLOGIC CONSIDERATION IN THE TREATMENT OF ALZHEIMER'S DISEASE

Part II

by Peter P. Lamy, PhD
Ilene H. Zuckerman, PharmD

Drugs for Treatment of the Alzheimer's Disease

Failed Experiments: No drug has as yet been developed that can be used to treat Alzheimer patients effectively. However, as the number of Alzheimer patients is increasing (AD patients, similar to other elderly, live longer than ever before) and as the disease is devastating to patient and family, a host of drugs have been tried. Among the failed experiments are RNA administration and use of magnesium pemoline (to stimulate synthesis of nucleic acid). ACTH has been tried, as it was thought that it may exert motivational effects, and so have hyperbaric oxygen and anticoagulants. At one time, there was high enthusiasm for high potency vitamins also.

Non-cholinergic Pharmacologic Treatment of Dementia: Multi-infarct dementia (MID) or arteriosclerotic dementia is probably the second most common cause of dementia in the Western world. Based on recognition of this factor, vasodilating agents were tried to increase cortical perfusion rates, particularly to ischemic areas. In the United States, papaverine, dihydroergotoxine, isoxsuprine, and cyclandelate (vasodilators) and methylphenidate and pentylenetetrazole (mild psychostimulants) have been approved for the treatment of senile cognitive decline. None have been shown to be of unequivocal benefit to AD patients. Furthermore, it is unlikely that these agents can dilate slerotic blood vessels and the vascular origin for AD is no longer widely accepted. There are other vasodilators that have been tested, including naftidofuryl, suloctidil, vincamine, and calcium channel blockers (e.g. nimodipine). Different from these agents is pentoxifylline, a hemorheologic agent, which was developed to improve erythrocyte flexibility, thus facilitating microcirculatory flow. Vasodilating agents can be divided into two

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Presented at the meeting of the Health and Education Council "Meeting the Challenge of Alzheimer's Disease and Related Disorders", Baltimore, Maryland, 1986

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Dr. Zuckerman is Assistant Professor, Department of Clinical Pharmacy, School of Pharmacy.

classes:

a. Primary vasodilators, having a direct effect: cyclandelate
b. Agents which may improve neuronal metabolism via enzyme systems, thus improving cerebral blood supply: hydergine

All of these agents, at various times with varied study groups, have been shown to be able to improve mood, alertness and behavior. A few investigators have found improvement in orientation, communication, and socialization. However, the majority of the studies involving these agents have shown negative results.

Other agents that have been tested include nicotinic acid and nylidrin, which were tested with similar negative results. It is important to realize that all of these agents can and do cause side effects in the elderly demented patients, including postural hypotension, headaches, vertigo, sedation and, possibly, hepatitis (papaverine), flushing, itching, light-headedness (nicotinic acid, cyclandelate) and nervousness, palpitations, and nausea (isoxsuprine, nylidrin).

Somewhat different results have been reported for hydergine, particularly when the dose was raised to 6 mg and a longer period of use was instituted. Hydergine is thought to act by increasing cerebral cellular metabolism resulting in improved microcirculation. It may also act by increasing cyclic AMP, promoting cerebral protein synthesis and increased aerobic metabolism. It has no particular side effects. Hydergine has been reported to improve mood, attitude, self-care, and physical symptoms such as anorexia, dizziness, and uncoordination.

It is important to note that some demented patients, probably less than one percent, may respond positively to thyroxine or vitamin B_{12}.

The Cholinergic Approach to Treatment of Dementia: AD involves abnormalities of several neurotransmitter brain systems, most commonly and importantly the cholinergic system. Abnormalities in that system correlate with the severity of AD. Pharmacologic enhancement of cholinergic activity has been tried at three different levels:

a. *Presynaptic agents,* which would increase acetlcholine (ACh) synthesis and release. The experimental use of choline and lecithin, both ACh precursors, has not been effective. At one time, deanol (Deaner, Riker) was thought to be a precursor of ACh and was, therefore, thought to be able to stimulate and enhance cholinergic activity. It did not work.
b. *Synaptic agents,* which would increase ACh by limiting its breakdown. Physostigmine falls into this category. It is an acetylcholinesterase (AChE) inhibitor, augmenting available synaptic ACh. It prolongs the action of ACh. Given intravenously, it causes significant but moderate transient improvement in memory tests. Orally, it yielded modest improvement in specific cognitive areas and overall functioning. The drug has a very narrow therapeutic window and a very short half-life. It is very toxic and can be given only in very small (and, therefore, ineffective?) doses.
c. *Postsynaptic agents,* which directly stimulate ACh receptors. Cholinergic agonists, such as RS 86, arecoline, and oxotremorine have yielded only modest results with significant side effects.

Other agents, such as bethanecol and analogues of ACTH, somatostatin and vasopressin are being tested. Vasopressin is thought to be able to mediate memory consolidation and retrieval. Serotonin agents, such as alproclate and zimelidine are being tested, as are such adrenergic agents as clonidine.

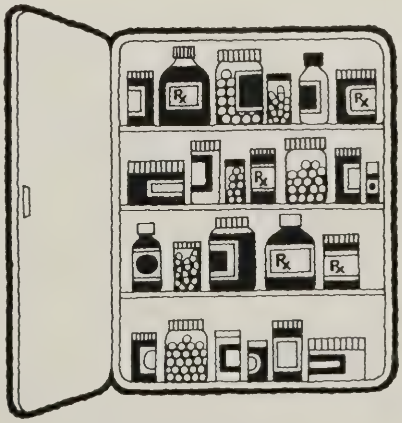
The Nootropics

The nootropics facilitate learning and memory in animal models. The most widely tested is probably piracetam. Some have been evaluated clinically in patients with cognitive decline, but results (perhaps because of difficult testing procedures?) have been equivocal so far. Those being tested are listed in Table V:

TABLE 5
Representative Nootropics

Piracetam
Oxiracetam
Pramiracetam (CI-879)
Rolziracetam (CI-911)
Aniracetam
CI-933
CI-844

It has been suggested that the nootropics might be more successful if used in combination with cholinergic agents, if the patient still has functionally intact cholinergic neurons.



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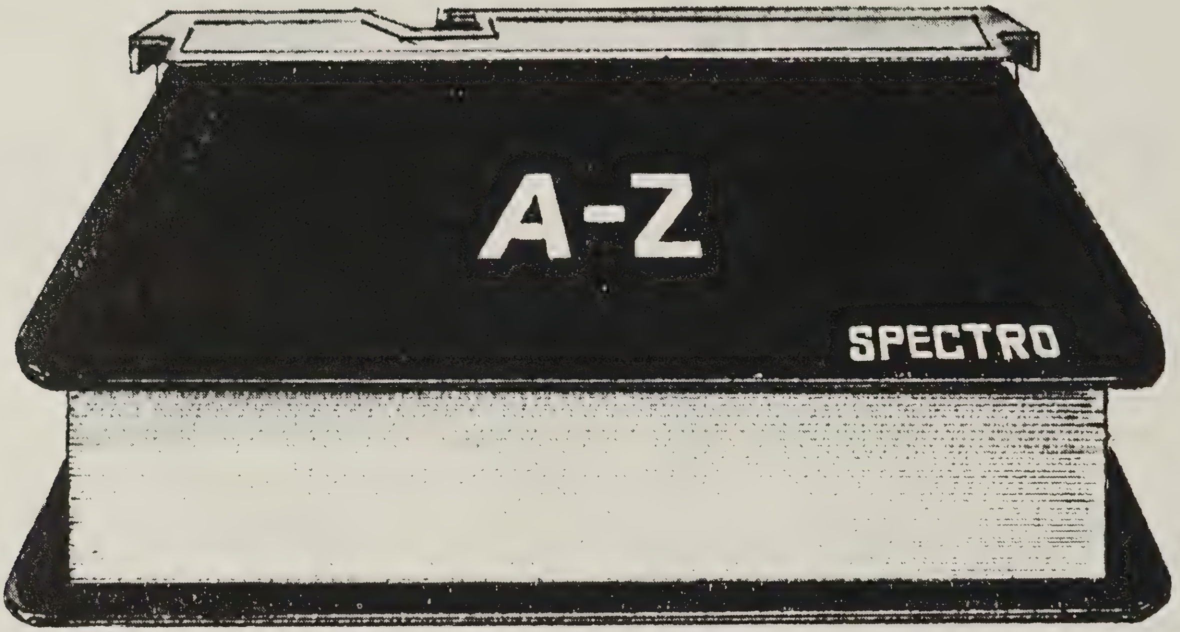

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This survey was developed by Sandoz Consumer Health Care Group, manufacturers of the Triaminic® brand of cold/cough products and the Ex-Lax® brand of laxatives, in association with the NARD Committee on Merchandising and Management, plus a panel of experts on pharmacy practice.

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After a minimum of 60 surveys are completed and returned, you will receive a confidential report within eight weeks. This report will summarize how your patrons rate your pharmacy and which services are most important to them.

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City State ZIP

Phone

Mail form to: Sandoz Consumer Health Care Group
P.O. Box 83611, Lincoln, NE 68501

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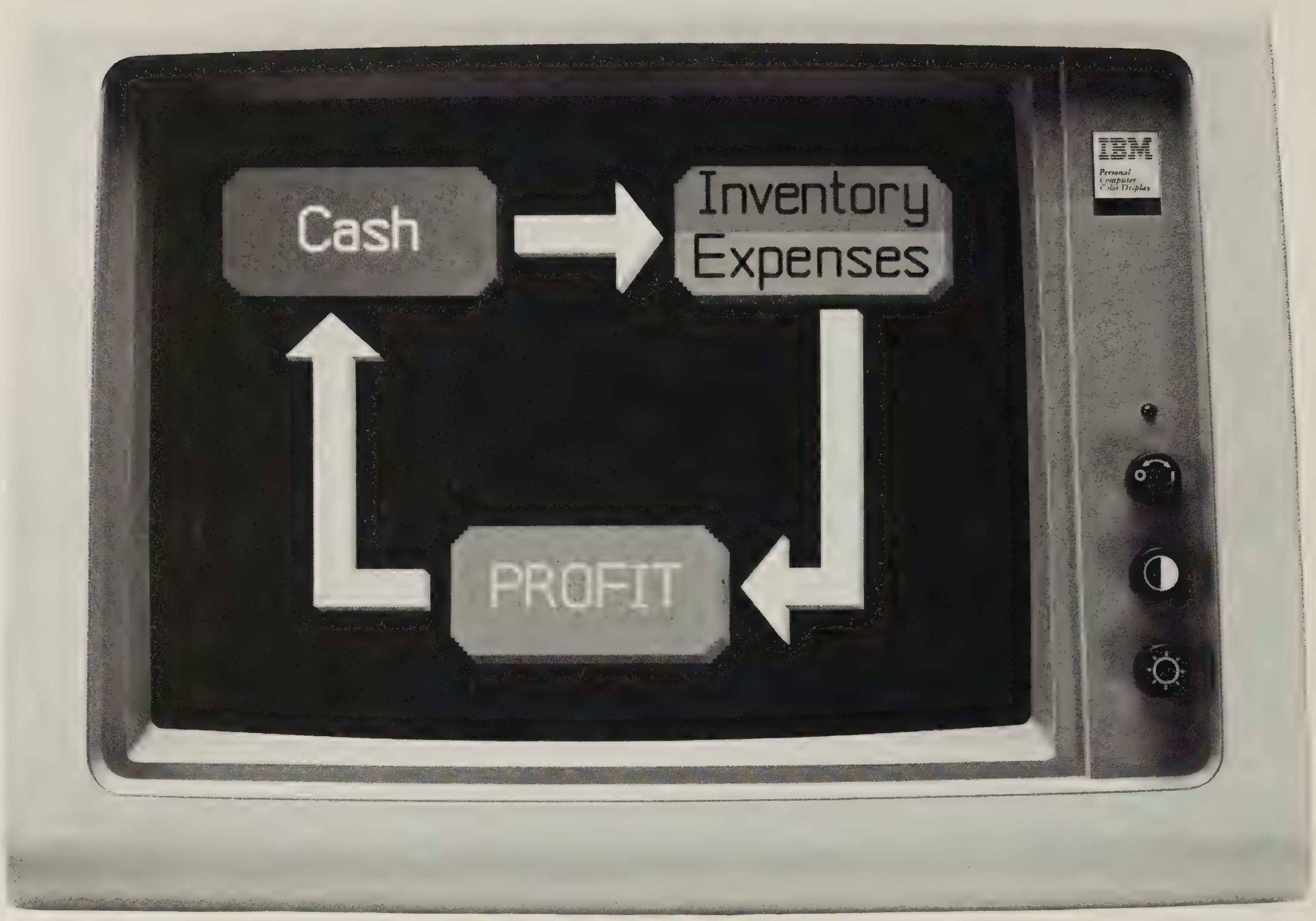

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Winning against mail-order.

by Jim Dickinson

It can be done. In Alabama, pharmacists have wrested a B. F. Goodrich employee benefits prescription contract away from a mail-order operation.

To do it, they used a small, wholesaler-operated local pharmacy service administrative organization (PSAO) that includes chain drug stores—Walker Drug's United Pharmacy Services, Inc.

It was a winning tactic, because something else was going for them as well: beneficiary dissatisfaction.

Benefits managers and third-party programs are slowly confronting this powerful new ingredient all across the country. Sometimes labeled "quality of care," it's being recognized as the ultimate cost-containment device, and handled correctly by pharmacy, it could be the retail profession's biggest healer.

By combining beneficiary dissatisfaction with a positive, patient-oriented determination, and focusing on programs that have adopted the mail-order option, the Alabama experience shows that retail pharmacies can win that lost business back when the contract comes up for renewal.

Indeed, in a perverse kind of way, if we can all hang in there long enough, mail-order options may be doing retail pharmacy a big favor—they're providing the long-suffering public with an uncomfortable "bench mark" against which regular pharmacy service and convenience can be measured with a sigh of relief!

It's a human frailty that we don't appreciate what we've got until it's gone.

At the same time, that frailty is providing lessons for the health bureaucracy, both private and public.

This past December, federal Health Care Financing (Medicare/Medicaid) Administrator William L. Roper, M.D., informed the annual Food & Drug Law Institute education conference of a radical new strategy he's adopted for Medicare: Quality of care!

As noted in this column previously, private-sector studies have been predicting that health managers would come to realize that quality of care is the optimum form of cost-containment.

Now Dr. Roper tells Washington health-drug lawyers at their annual meeting that he wants "to further improve the quality of care under the Medicare and Medicaid programs" by developing a better measure of quality, a measurable outcome. HCFA, he said, now wants to know: Does the patient get better over time?

What stronger indicator could you want that the cost-containment juggernaut is evolving to a new, intelligent level of sophistication—a level that cannot be attained by mail-order prescriptions?

Being careful not to alarm and alienate the old folk who feel they get good service from AARP pharmacies, the time is now ripe for pharmacy to pound away with its favorite message in the employee benefits arena, cautioning against out-of-state, anti-quality, bargain-basement prescriptions for employees.

The distinction is tactically valid if you're prepared to separate chronic maintenance therapy for housebound old people from all other pharmaceutical care.

Ask your local employers if they really want their employee benefits package to take money and jobs out of your community and state.

Ask them what happens if their employee forgets to get the prescription refilled just before a holiday or weekend, or when they're going out of town on business?

Ask what happens if the mail-order pharmacy makes a mistake, and accidentally sends the wrong prescription, or if the postal service delays or loses the package?

Ask what happens if the employee develops an unexpected sensitivity to the drug, and has to be quickly switched to something else?

Ask how much absenteeism they can afford when illnesses result from erroneous treatments that local pharmacists can't help prevent or correct.

The time has never been better to ask such questions—and to keep on asking them.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Convention Awards

The Awards Committee of the Maryland Pharmaceutical Association is soliciting nominations from the membership for two prestigious awards which are presented to pharmacists at the Annual Banquet. The Committee decided that more membership input into the Awards process would be appropriate. The two Awards are:

BOWL OF HYGEIA This award is presented annually through the cooperation of the A. H. Robins Co. to a pharmacist who has compiled an impressive record in the area of community service.

MPhA ACHIEVEMENT AWARD This recently instituted award is given to a pharmacist who is distinguished in the area of contributions to the profession of Pharmacy.

Nominations for either of these two awards may be sent to the Awards Committee for consideration. Nominations must be in writing and should outline the qualifications of the individual for the award being considered. Nominations are kept on file each year and may be considered by the Awards Committee in future years. Nominations or inquiries about the nominating process should be sent to the M.Ph.A., 650 W. Lombard Street, Baltimore, Maryland 21201.

Convention Resolutions

The Vice Speaker of the House of Delegates, Brian Sanderoff, also serves as Chairman of the Association's Resolutions Committee. The Committee will be meeting soon to consider issues and resolutions for the Annual Convention of the Association, June 21–25, 1987 in Ocean City, Maryland. In order to allow for greater membership participation in the resolution process which forms the basic policy making structure of the Association, the Committee is soliciting input from the membership in the form of suggested resolutions or resolution topics. Resolutions may be sent to the Association at this time with any background or supporting information necessary. They should be sent to the M.Ph.A. Resolutions committee, 650 West Lombard St., Baltimore, Md. 21201.

NEW MEMBERSHIP BENEFIT

Working with the Mid Atlantic Food Dealers Association, the MPhA is pleased to announce a coupon redemption program designed for rapid turnover and easy administration. Pharmacists will receive the face value for all valid coupons submitted plus the following: batches of 500 coupons and under—$.02 per coupon; 500 to 1000 coupons—$.02.5 per coupon; and batches of 1000 coupons and over—$.03 each. This special Coupon Redemption program also helps the MPhA. The Food Dealers Association's has a very large Coupon Redemption program for its member grocery stores. Take advantage of the security, rapid turnover and outstanding reimbursement available to you for the first time.

COUPON REDEMPTION PROGRAM

Call Mary Ann at the MPhA office (301-727-0746) to receive details by mail and your first mailing packet.

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SAVE 15¢
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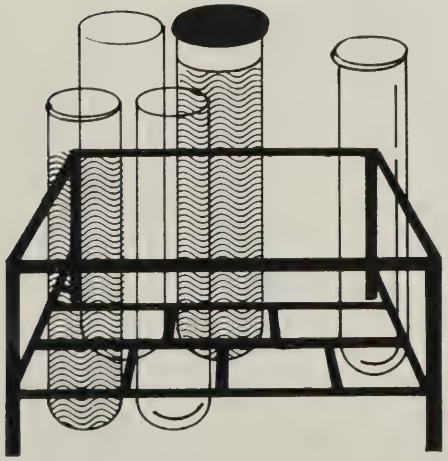
VE 20

MPhA Continues A New Member Service and Journal Feature

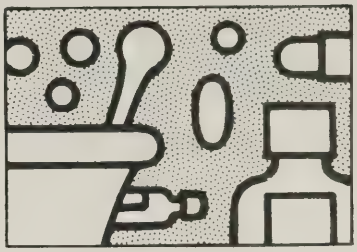
The patient education aid on the right is part of a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, MD. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other information, place such information so that it covers the artwork in the upper right hand corner.



Things You Should Know FOR YOUR GOOD HEALTH



Vitamin C: The Controversy Continues

With all the talk about preventive medicine and finding a cure for the common cold, vitamin C became a star of the megadose movement. Millions of people are swallowing billions of vitamin C tablets to ward off and decrease the severity of the common cold. Claims have been made regarding the ability of this vitamin to prevent and cure more serious diseases, including cancer. People are using vitamin C as a drug with the belief that it will aid them. However, there are no conclusive studies of its benefits for these diseases.

Like all drugs, vitamin C has potential risks as well as benefits. Some people have become ill from self-medicating themselves for conditions with unproven remedies. Vitamin C, also known as ascorbic acid, aids in the formation of collagen, a fibrous tissue which appears throughout the body. It helps maintain capillaries, bones and teeth, and it protects other vitamins from oxygen breakdown. Due to its antioxidant properties it is used as a food additive. It is added to bacon to block the formation of cancer-causing nitrosamines. There are current studies investigating a similar action in the body.

The daily adult requirement of vitamin C is 60-70 mg. It is not produced in the body. Children should receive 40 mg daily and infants who do not have ascorbic acid supplements in their formula should receive 35-50 mg daily.

The daily requirement can easily be fulfilled by a variety of foods. Foods that meet the daily requirement include: one medium-size orange, half a cup of orange juice, one cup of grapefruit sections, six ounces of grapefruit juice, one cup of strawberries, half a cup of pineapple chunks, half of a cantaloupe, half a cup of raw green pepper, two medium-sized tomatoes, one medium sweet or white potato, half a cup of cooked broccoli, and six ounces of cooked cauliflower.

Vitamin C is water soluble and some of it evaporates when heated. During the freezing process, there is little or no loss of vitamin C. Therefore, orange juice prepared from frozen concentrate contains the same amount or more vitamin C than freshly squeezed juice. Vitamin C consumed in concentrations greater than the daily body requirements is excreted in the urine.

Linus Pauling, who popularized the use of vitamin C in preventing and treating the common cold, recommended 1-5 grams daily as a prophylactic measure and up to 15 grams daily to treat a cold. Many studies conducted after Pauling's initial research have shown no effect of the vitamins on the number of colds people get, but may lessen the severity or symptoms of colds.

In certain people, megadoses of vitamin C can precipitate gout and the formation of kidney stones. It can also cause abdominal pain and diarrhea. Large doses can also block the action of blood-thinning medications, may increase stomach ulceration caused by aspirin, and may interfere with the metabolism of some drugs.

The best way to protect yourself against adverse drug effects is to ASK YOUR PHARMACIST about any medication, prescription or over-the-counter drugs you are taking. Nonprescription drugs, including vitamins, may lead to serious consequences.

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The Industry Relations Committee Says:

Make February

The Month

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Merchandise

The Industry Relations Committee of the Maryland Pharmaceutical Association formed a subcommittee to study the issue of a Model Return Goods Policy. It was the feeling of the Committee, which is made up of manufacturing representatives and practicing pharmacists, that the policy should be fairly comprehensive and yet, provide some guidance and consistency in this area. The goal of the Committee was to develop a policy which could be endorsed by the Association in an attempt to establish a standard and which would be acceptable to both manufacturers and retailers.

The Committee recommends that members retain this page from the journal and refer to the following MPhA adopted policy whenever a question concerning returning merchandise arises. In addition, the Industry Relations Committee serves as an ombudsman whenever members refer a problem concerning this subject in writing to it.

MODEL RETURN GOODS POLICY

1. **New prescription drug products shipped to the pharmacy automatically by the manufacturer or wholesaler may be returned at any time for credit or exchange.**
2. **Regardless of expiration dates products may be returned for credit or exchange at any time, providing they are sealed, intact, original packages.**
3. **For patient protection, open packages of prescription drug products which are outdated may be returned for at least partial credit.**
4. **Authority for returns may be required by the pharmaceutical manufacturer or wholesaler—a form should be provided to the pharmacy.**

SAMPLE FORM to Return Merchandise

TO: (Name of Manufacturer)
Address — including the name of Town, County,
State and Zip Code

(Note — the above as well as the policy for making returns may be located in the NWDA list of Mfgs. in January 1977 edition of the American Druggist Blue Book).

Please grant us authorization to return the following pharmaceuticals of your manufacture as per your policy:

It is best to list the items — listing complete packages as well as open containers. If a return of a schedule 2 is requested, be sure to give exact count and hold these aside as they usually will send a narcotic form. (Because of mail rates, it may be less expensive to have the drug inspectors destroy them.)

Note — If in their reply, they say they do not accept open containers — or — partially filled ones, call their attention to the fact that for the protection of the patient, as well as the pharmacist and the manufacturer, you believe it best they change their policy to permit them to accept them for credit.

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The 3rd edition of the ***RETURN GOODS POLICY MANUAL*** can expedite the process of returning your unsalable inventory. The MANUAL contains the current return goods policies of over 150 pharmaceutical manufacturers in a standard format. The policies are in a three ring binder to allow for updates and additions.

The ***RETURN GOODS POLICY MANUAL*** provides information on:

*who to contact if a sales representative is not available

*company addresses and phone numbers

*what items are and are not returnable

*the procedure for returning items

*the type of compensation to the pharmacy, i.e. credit or exchange

*transportation charges

*company disclaimers

**and much more.

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make your money work for you.

______ Yes, Please send me ______ copy(ies) of the third edition of the ***Return Goods Policy Manual*** for $30.00 each (includes postage and handling).

______ Enclosed is a check payable to the ***Return Goods Policy Manual.***

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Mail to:

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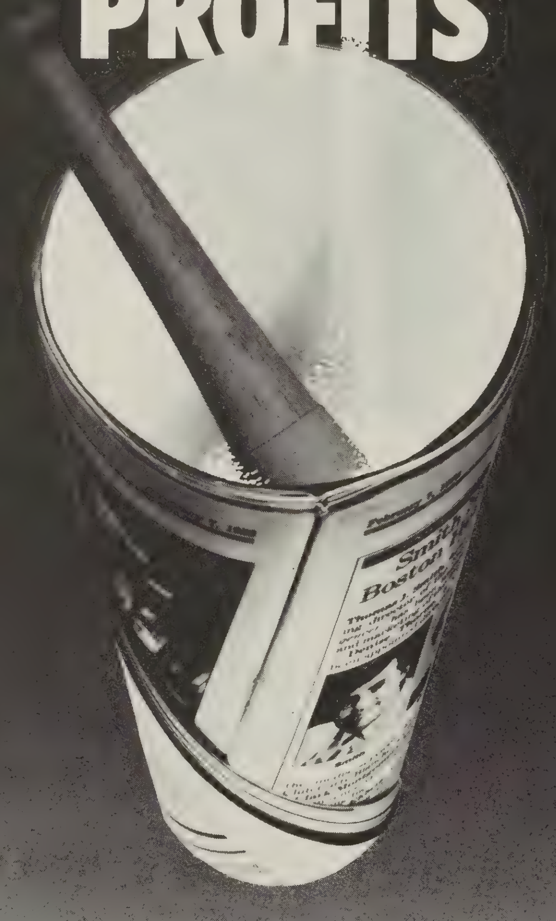
(Please allow 4 to 6 weeks for delivery.)



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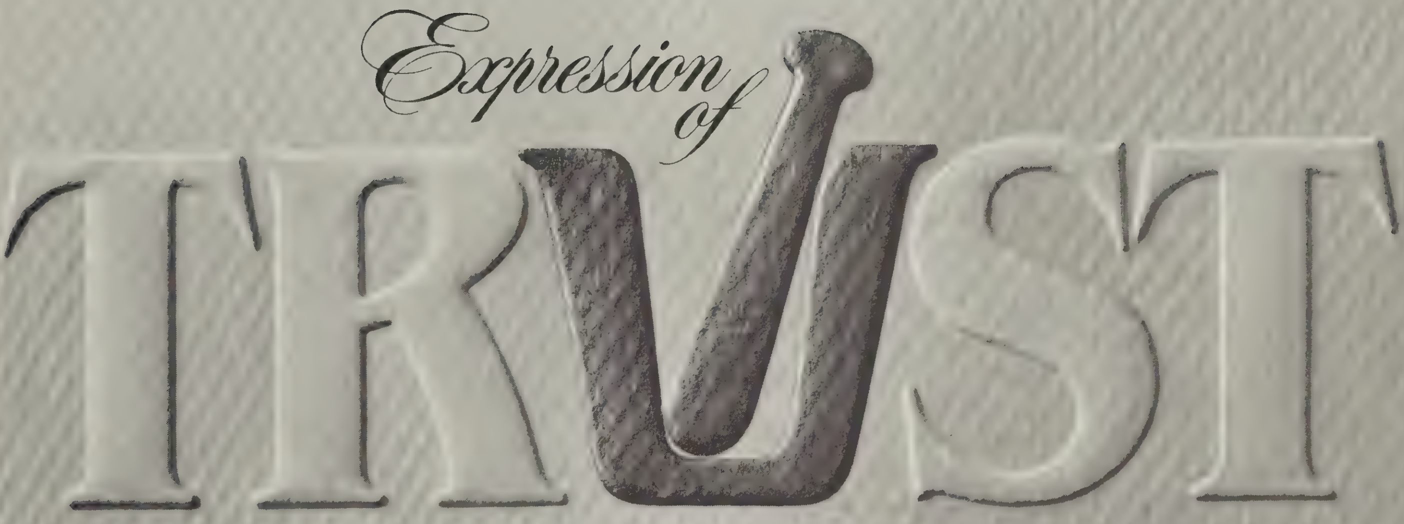

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CANCER: NEW TECHNIQUES IN EARLY DIAGNOSIS INCREASE SURVIVAL TIME

Cancer is the name given to more than 100 diseases in which cells grow at abnormal, uncontrolled rates. The cells can invade and damage normal tissues and organs at their point of origin, as well as spread to other parts of the body in a process called *metastasis*.

The United States National Cancer Institute estimates that 1984 will bring more than 870,000 new cancer cases in the U.S., divided more or less equally between men and women. Some 450,000 Americans will die of cancer this year, making cancer the second leading cause of death according to the American Cancer Society. Estimated cancer deaths worldwide are nearly 10 times this figure, or 4 million annually.

In the U.S., the five leading cancers in adult males are lung (22 percent), prostate (18 percent), colon/rectum (14 percent), urinary tract (9 percent) and blood/lymphatic (8 percent).

In U.S. women, the most common cancers are breast (26 percent), colon/rectum (15 percent), uterus (12 percent), lung (10 percent) and blood/lymphoid (7 percent).

When American children under 15 are stricken, it is most often with leukemia (30 percent), nervous system cancer (26 percent) and lymphomas (lymph node cancers, 14 percent).

An early clue to the role of diet, habits and environment in causing cancer emerged from comparing statistics of cancer deaths in different countries. For instance, stomach cancer is the leading cause of cancer deaths in Japan, while death due to lung, breast and prostate cancer is significantly lower there than in the U.S. Cancer statistics on Japanese adults who immigrated to the U.S. as children and adopted the U.S. lifestyle resemble those of American adults.

While the types of cancer in Canada are similar to those found in the U.S., statistics from Europe show wide variations in the frequency of deaths from different types of cancer. For instance, Ireland is the leader in colon/rectum cancer, while Scotland is first in lung cancer deaths, and Denmark the leader in fatal breast cancer.

Changing Patterns: Over the last 25 years, death rates due to different types of cancer have changed significantly. Most notable has been the sharp rise in lung cancer deaths—an almost 200 percent increase in men and more than 400 percent in women. (See Figure 1.) This has been linked to cigarette smoking, which is believed to be the main reason for the increased cancer rate in the U.S. However, there has been a steady decline in stomach cancer in both sexes and in colon-rectal and uterine cancer in women.

Improvements in Survival: One measure of increased success in the battle against cancer is the percentage of people who survive five years after diagnosis. The figure is up from about 33 percent in the 1960s to 39 percent for people diagnosed in 1973 to 1980. Factoring in normal life expectancy—including other causes of death—raises the actual figure to 48 percent as compared with 40 percent in the 1960s. The greatest improvements in survival of adults have occurred in Hodgkin's disease (a type of lymphoma) and certain leukemias, prostate and uterine cancers. Some increase in survival is observed in almost all cancer.

"Childhood cancers show the most dramatic decline in deaths and the greatest increase in five-year survival," says George L. Royer Jr., M.D., a pediatric oncologist with The Upjohn Company.

"The five-year survival rates for childhood Hodgkin's disease, eye, kidney and brain (glioma) cancer are now roughly 90, 85, 70 and 59 percent, respectively. And acute lymphocytic leukemia now has a five-year survival rate as high as 75 percent in some special treatment centers," he says. "Of these five-year survivors, two-thirds (that is, 50 percent of all children treated promptly after diagnosis for acute lymphocytic leukemia) appear to be cured.

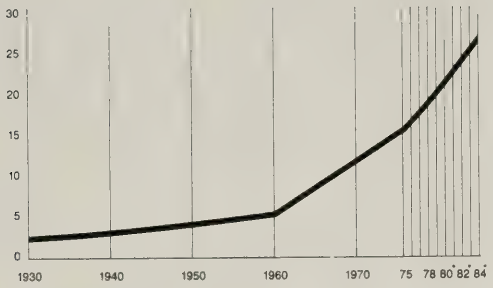
"Fifteen years ago, acute myelogenous leukemia, more frequent in adults, had a survival time of weeks to months for only a few patients; most died almost immediately. Now, in major cancer treatment centers, 75 percent of these patients can expect to go into remission, with 20 percent living disease-free for five years. Although too early to say definitely, these five-year survivors appear to be cured. This dramatic increase in remission rate and probable cure in 20 percent is due in large part to the introduction of Cytosar-U sterile powder (cytarabine) into the treatment schedule," says Dr. Royer.

Instant Access to Information Enhances Efforts Against Cancer

A physician diagnosing a patient with a rare form of

FIGURE 1 **LUNG CANCER DEATH RATE SOARS AMONG U.S. WOMEN**

Age-adjusted rates per 100 000 population

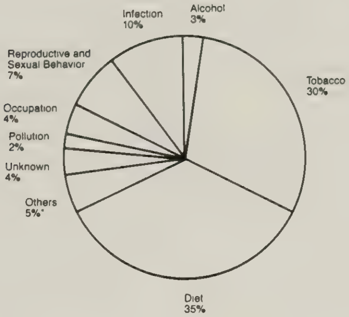


*1980-84 figures are estimates

Data source National Cancer Institute

FIGURE 2. **U.S. CANCER DEATHS ATTRIBUTED TO VARIOUS RISK FACTORS**

Figures cited are best estimates from survey of recent studies



*These include ultraviolet radiation, industrial products and medicines, X-rays and other medical procedures

Data source Doll and Peto, "The Causes of Cancer," *Journal of the National Cancer Institute*, Vol 66, June 1981

cancer now can use a telephone and computer terminal to access a U.S. National Cancer Institute (NCI) data base and obtain the latest information on possible treatments. Known as PDQ (protocol data query), the system also provides the names of consulting experts using each treatment. Moreover, it incorporates the latest approved treatments and can be updated rapidly by computer.

Providing information is a key function of the NCI. Its Office of Cancer Communications collects and distributes educational materials to patients, the public and educators of healthy professionals. Also in the U.S., the American Cancer Society (ACS), a voluntary organization, carries out a similar program via symposia and publications.

Immediate access to new research and treatment information on a global level is provided by the International Cancer Research Data Base (ICRDB). This keeps track of published literature on cancer treatments and research projects. The reports can be obtained instantly at 1,600 locations in the U.S. and 13 other countries. ICRDB also publishes periodic summaries of research, cancer treatments and epidemiology for worldwide distribution.

Cancer Detection

Early detection of cancer, before it spreads to other sites, is vital to successful treatment. A great deal of research has been devoted to detecting cancer in symptom-free people. Simple tests that can be performed at home are but one precaution that could save thousands of lives.

Breast Self-Examination: A five-year ACS/NCI study, the "Breast Cancer Detection Demonstration Project," completed in 1981, shows that breast self-examination (BSE) as part of a regular screening program can detect cancer in its early stages. The report notes that BSE performed alone or with mammography (breast X-ray) when a lump was felt was responsible for discovering 56 percent of the tumors during the five-year period. Eighty percent of these tumors did not involve the lymph nodes and were expected to be curable. The ACS recommends monthly BSE, starting at age 20, as a regular part of prevention.

Testicular Self-Examination: Testicular cancer is one of the most common cancers in men between ages 15 and 35. When treated early, it is curable. Ignorance about the existence, symptoms and detection of this cancer is wide-spread. In a 1983 study of 266 male college students, only 16 percent had heard of testicular self-examination (TSE) and only a third of that group practiced it. Awareness that the common symptoms of testicular cancers—lumps, swelling and pain—can be detected by TSE would save lives. Unfortunately, most testicular cancer is far advanced when finally seen by the physician.

Watch for Warning Signs: Many cancers give early warning signs that should be a signal for a checkup. Advertised widely as part of the ACS public information program, the signs include:

- change in bowel or bladder habits
- a sore that does not heal
- unusual bleeding or discharge
- thickening or lump in the breast or elsewhere
- indigestion or difficulty in swallowing
- obvious changes in a wart or mole
- nagging cough or hoarseness

Screening and Diagnostic Tests Performed by the Physician

The screening and detection methods now available vary from the simple and inexpensive, such as the PAP test, to complex analyses that require a nuclear magnetic resonance spectrometer—an instrument priced at more than $1 million.

Screening tests are those used to detect the presence of possible disease indicators among individuals in a large and presumably asymptomatic population; *diagnostic tests* are those that are used to determine just what is causing an individual's symptoms or other findings.

PAP Test: This test has cut the death rate from uterine cancer dramatically in the last 40 years. As part of the routine pelvic exam, the physician removes a sample of cells from the cervix and uterus for microscopic examination. This method efficiently detects early cervical cancer, but picks up only 50 percent of uterine lining (endometrial) cancers.

Hemoccult Test: The hemoccult searches for traces of blood in the stool and is being standardized for mass screenings. Properly done, it can detect cancers of the bowel before symptoms appear. Currently, up to 50 percent of positive hemoccult tests are false positives —due to other causes. A positive result must be followed by confirmatory tests. False negatives also are a problem. However, in a British study that screened over 10,000 subjects, the test detected cancer of the bowels at a rate 3.6 times greater than in the unscreened control group.

Colonoscopic Biopsy: A positive hemoccult test often is followed by examination with a flexible fiberoptic colonoscope. Inserted through the rectum, this tubular instrument can follow the bends of the intestine. The colonoscope's plastic or glass fibers have special optical properties that allow the doctor to look at the interior of the gut. If a growth is detected, it can be snipped out with a noose-like device at the end of the colonoscope and then examined microscopically. Use of the flexible colonoscope can lead to discovery of more than 90 percent of bowel cancers.

Mammography: One of the most powerful tools in the early detection of breast cancer is mammography. It is a type of X-ray analysis that can pinpoint extremely small localized cancers. The five-year ACS/NCI study showed that in the 40 to 49 age group, 35.4 percent of the cancers could be detected only by mammography and not by a physical exam of the breast. These cancers had a below average lump size and fewer involved the lymph nodes. Both factors bode well for favorable treatment.

The newest mammography machines not only use lower amounts of radiation than the original models, but are more sensitive. Thus, the ACS now advocates mammography at least biannually for all women 40 and older. The NCI, taking a more conservative stance on X-ray exposure, makes this recommendation to women 50 and older—the highest risk group—and for women with a personal or family predisposition to breast cancer. Women 35 to 40 are urged by the ACS to have one base-line mammogram.

Computerized Tomography (CT): Unlike conventional X-ray, CT scan provides three-dimensional information that includes data on tissues other than bone. Cancer detection by CT scan is fast and non-invasive. The scan is also used to follow the course of therapy and to determine whether or not tumors are operable without exploratory surgery. Due to cost and complexity factors, CT scans are not a practical approach to screening for cancer.

Nuclear Magnetic Resonance (NMR): NMR is a sensitive device for detecting dead or degenerating cells, blockage of blood flow and cancers. The method is non-invasive and does not use potentially harmful X-rays. Instead, radio waves and a magnetic field delineate the tissues. This method has another advantage over the CT scan: If the cancerous lesion is very small and has the same X-ray characteristics as normal tissue, a CT scan won't find it. NMR detects subtle chemical changes in the lesion that precede gross physical changes. At this time, NMR is a sophisticated research tool whose potential applications to the clinic are just beginning to be understood.

Monoclonal Antibodies: Monoclonal antibodies—pure preparations of defensive immune system compounds from human or animal blood cells—may prove to be revolutionary tools for detecting minute traces of cancer in samples of tissue or body fluid. Produced from hybrid cells by new biotechnology, monoclonal antibodies can attach themselves to particular spots on cancer cells called *tumor-associated antigens*. If a dye molecule is attached to the antibody, the researcher can selectively stain cancer cells on a microscopic slide.

Alternatively, *immunoscintigraphy* involves attaching a radioactive isotope to the antibody and injecting the mixture. The location of cancer cells is found by photographing the patient with film that is sensitive to the radioactivity of the isotope.

Tumor-associated monoclonal antibodies have been developed for melanoma (pigmented skin-cell cancers) and cancers of the lung, breast, ovary, colon and liver. One monoclonal antibody now available can detect prostate gland cancer. It is expected to be years before techniques based on monoclonal antibodies can be used routinely in the clinic.

All of these technologies are aimed at saving lives by catching cancers before they metastasize.

"A number of excellent diagnostic tools and tests for cancer now exist, and many more are in the works," says Robert H. Earhart, M.D., Ph.D., of The Upjohn Company. "But the benefits of these come primarily when individuals are alert to their own body signals, perform self-examinations and track down the cause of any suspicious signs with a doctor's checkup."

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*According to the 1985 National Prescription Buyer Survey by Market Facts, Inc.

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LETTERS

Dear Dave:

Recently George Wagner, Jr. died after a one year battle with severe refractory congestive heart failure. George was a fellow classmate of mine, a Fraternity Brother, and a graduate of the Philadelphia College of Pharmacy and Science. He has worked as a pharmacist on the Eastern shore for many years, initially at Drug Fair in Chestertown and more recently as the owner of Unicorn Pharmacy in Millington Maryland. For those of you that knew George, he was a very outgoing, gregarious, individual who loved life and interacting with people. In the course of his illness he has accrued significant medical expenses in excess of $30,000.00 which are not covered by his insurance policy. A fund has been set up at the Millington Bank to help his family with the significant expenses. George is survived by four children, ages ranging from one year to ten years of age, and by his wife Joanne.

It is obvious that this untimely death in this young person's career has left devastating consequences to his family and friends. I therefore would like to solicit your support by making a donation to the George Wagner Memorial Fund to help a fellow pharmacist's family who is in dire need of support. Please send the contributions to the address listed below. On behalf of George and his family, I sincerely wish to express my sincere gratitude for your generosity.

George Wagner Memorial Fund
c/o Millington Bank
Millington, Maryland 21651

Sincerely,
Thomas S. Sisca, Pharm. D., FCCP

Dear MPhA Board Members;

My participation as a board member for the Maryland Pharmacists Association has been quite rewarding both personally and to my professional career. In the past one and one-half years, I have had the privilege to work with many outstanding leaders in pharmacy. The knowledge that I had gained about the problems and challenges facing pharmacy will certainly help me in my future plans. I will always support the pharmacy associations and plan to take an active role whenever possible. I find it personally rewarding and an excellent way to meet new people.

I especically appreciate the MPhA for their active support of the Student American Pharmaceutical Association, Maryland Chapter. The MPhA has always supported us in many ways including reduced association dues, financial support for conventions, support and advice for SAPhA functions, and encouraging students to become involved in pharmacy associations. The Maryland chapter of SAPhA feels very honored to have a position on the Board of Trustees of MPhA. As in the past, we will continue to exercise our position with professional integrity and to represent pharmacy students.

My time on the board has been very fruitful for both myself and SAPhA. I have grown professionally and my involvement has set the base for my future plans and projects. Having served this position, I feel confident about my performance and ability to become involved in issues and affairs concerning pharmacy.

I am sure that MPhA will always support SAPhA and its activities. The newly elected leaders in SAPhA will do a fine job to represent our chapter. We look forward to many years of continued support and closer ties with the MPhA. It has been a great honor to serve on the Board of Trustees and I thank the MPhA for allowing SAPhA that position.

Professionally Yours
Thomas P. La Martina
President, Student APhA,
Maryland Chapter (3/85~)11/86

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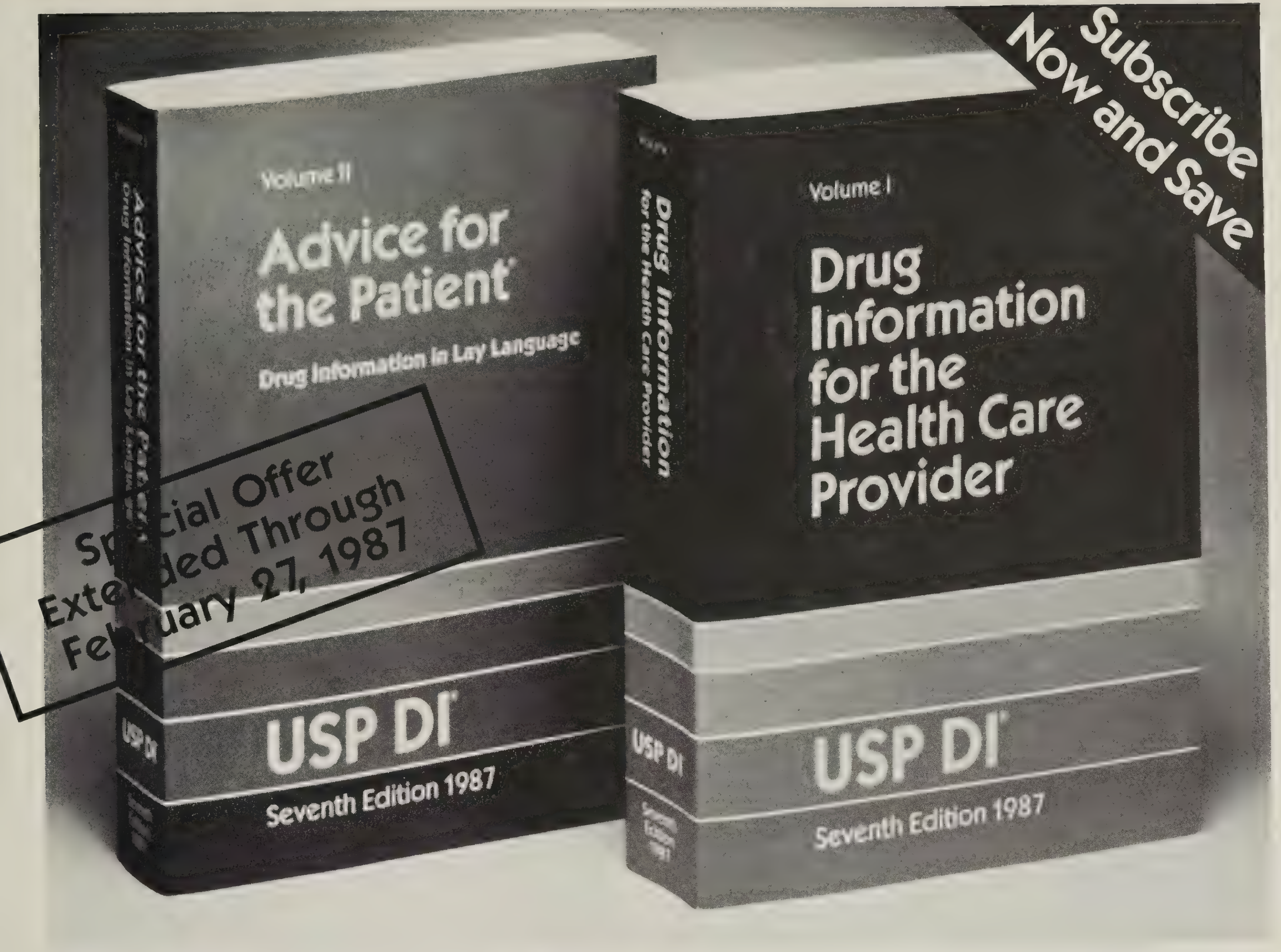
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The Seventh Edition of *USP DI* is scheduled for publication February, 1987. Please allow 4–6 weeks for delivery from publication date.

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Tips for Easing the Strain of Standing

Which would you rather do — walk for eight hours or stand for eight hours?

Your feet, believe it or not, would prefer the walking. Standing, for reasons we'll be seeing in a second, can be a veritable marathon.

"Standing involves 100 percent of foot use while walking requires only about 50 percent," says California foot specialist Dr. Dennis Augustine. "When you walk, your feet alternate the load, with one foot getting a rest half of the time. But when you stand, the load is constant."

Add to that the fact that standing encourages very little blood flow for the amount of strain it puts on the feet and you begin to understand why the U.S. Department of Labor Statistics is telling us that foot problems rank right up there with upset stomach and headache when it comes to making 9 to 5 feel like 9 to infinity. Over one-quarter of all accidents in the industrial workplace relate in some way to fatigued feet, the result of which has been a kick in the shins to the economy of some $500 million annually.

So what can be done about the hazards of standing? We asked Dr. Augustine what he would recommend for easing the burden of remaining upright, and here are the tips he came up with:

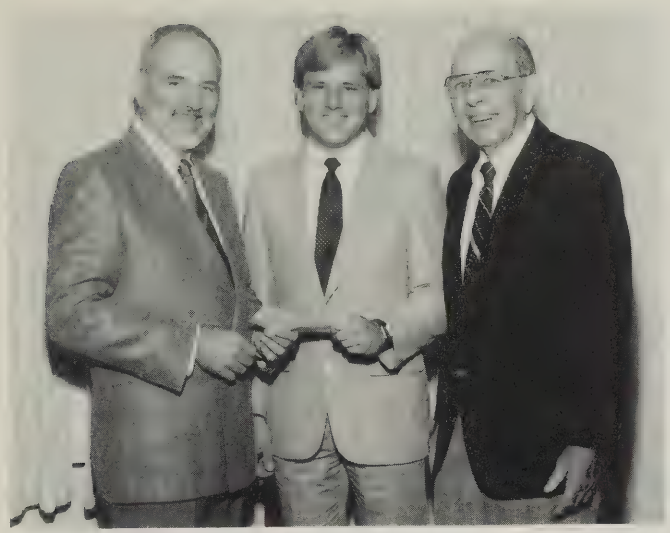
- Of utmost importance, he said, is a good shoe — one that provides good support but also good cushioning: hence the advisability of a quality insert for padding. The shoe also should have a very **low** heel and a wide toebox to allow toes plenty of room to wriggle. Plastic and rubber shoes are a no-no because they allow feet very little ventilation (the result of which can be undue sweating, heat fatigue and even athlete's foot). And when we asked Dr. Augustine about the advisability of running shoes for daily wear, he said, "Sure, as long as your employer approves and the running shoe is a good one with a firm enough outer sole to provide good support."

- Also crucial, Dr. Augustine said, are proper socks. Cotton is best because it absorbs moisture best. And don't think they have to be skin tight for "support." Too much "support" can wind up cutting off circulation — especially for women who wear tight panty hose or, worse yet, stockings supported by garters. To ease the strain of standing, feet need all the blood they can get.

- Keep your feet dry. "Go so far as to change your socks at lunchtime if sweating is a problem for you," Dr. Augustine said. "Moisture breeds bacteria, which can lead to a variety of foot infections." Another good idea is to dust feet and the inside of shoes with talcum powder to keep feet dry.

- Keep your feet active. Feet need adequate blood flow, remember, so anything you can do to keep the muscles of the foot active is advisable: Raise up onto your toes as often as you can; roll over onto the sides of your feet occasionally; pick one foot up off the floor and wriggle it inside that shoe as wildly as possible. (No one will know.) "Or even get yourself one of those rubber doormats with all the little rubber nipples to stand on," Dr. Augustine said. The mat will not only provide cushioning but also keep your feet active as they constantly try to adjust to what Dr. Augustine termed the mat's "variable terrain."

- How about pampering feet **off** the job? The foot is quite human in that it responds very favorably to simple TLC, Dr. Augustine says. He recommends massaging your feet with lanolin, cocoa butter or baby oil. Or if you don't care for the greasies, try rubbing alcohol. A most soothing foot soak can be concocted of warm water and vinegar (one-half cup vinegar to two quarts water) or warm water and Epsom salts. Calluses, Dr. Augustine said, can tenderly be removed with pumice stone (available at your local pharmacy), but as for anything more serious (i.e., corns, bunions and pains that persist more than a day or two), that could be the time to see your doctor.



Facts and Comparisons has awarded its 1986 Post Graduate Drug Information Scholarship to Jon E. Maesner (Center). Gene Schwach (left) is President of *Facts and Comparisons* and Erwin Kastrup is the Founder.

It's Not Too Early to be thinking about the MPhA Convention—June 21–25, 1987 at the Sheraton Hotel in Ocean City, Maryland and a repeat of the Annual Crab Feast at the Berlin Firehall.

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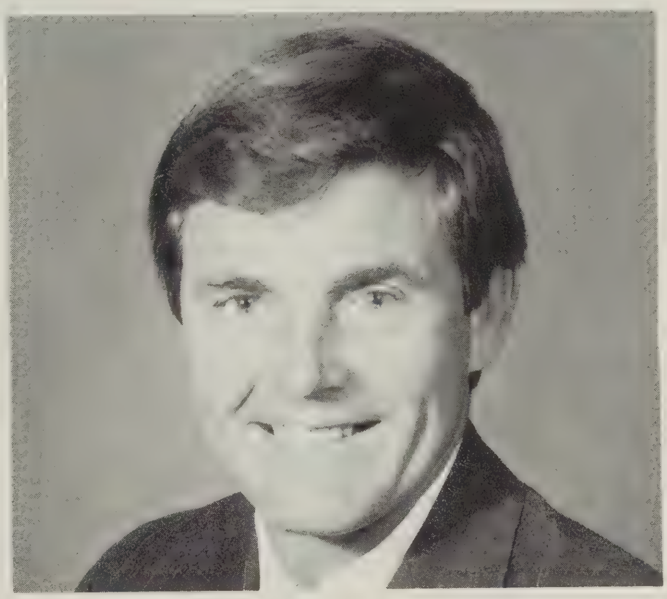
The MPhA Drug Utilization Program has been established for the Medicaid Program. Pharmacists and Physicians will soon be receiving "Information Alert" letters with this symbol from the DUR Program.



The 1987 Convention will feature a Continuing Education Program by David L. Schmidt sponsored by the Upjohn Company. Once again, it will be a joint Convention with the Delaware Pharmaceutical Society.

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

The new Sandoz Consumer Health Care Group, a combination of Dorsey Laboratories and Ex-Lax® Pharmaceuticals, announces the Pharmacy Patron Survey, a unique, cost-free service to community pharmacies. Now, for the first time, community pharmacies can evaluate the attitudes of their clientele concerning the quality of their pharmacy services. This survey will also serve as a market research tool to help pharmacies develop their future marketing programs.

The survey was developed by Sandoz Consumer Health Care Group in association with The National Association of Retail Druggists and a consultant panel that includes:

William H. Campbell, Ph.D., Professor and Chairman, Department of Pharmacy Practice; University of Washington School of Pharmacy

T. Lee Hageboeck, Ph.D., Associate Professor of Pharmacy Administration; Butler University College of Pharmacy

Richard A. Jackson, Ph.D., Professor and Chairman, Department of Pharmacy Administration; Mercer University School of Pharmacy

Elgene Jacobs, Ph.D., Assistant Professor of Pharmacy Administration; University of Nebraska College of Pharmacy

Arthur A. Nelson, Ph.D., Dean and Professor of Pharmacy Administration; Idaho State University College of Pharmacy

William N. Tindall, Ph.D., Vice President of Professional Affairs; The National Association of Retail Druggists

Each participating pharmacy will receive an individual, confidential report summarizing how patrons rate their pharmacy and which services are most important to them.

The survey was test marketed in the state of Washington with the assistance of Ray Olson, State Executive Director. Based on the success of this test market, the survey is now being made available to all community pharmacies on a national level.

The Pharmacy Patron Survey will be announced in major national and state pharmacy journals. Pharmacists wishing further information about this program should contact Lon D. Lowrey, 1-800-228-4575.

calendar

Feb. 8 (Sun)—MPhA MID YEAR MEETING, Annapolis Hilton
Feb. 16–24—Alumni/School annual giving Phonothon
March 8—BMPA Annual Dinner Dance
March 15—CECC Seminar "Airway Disease"
March 15–21—National Poison Prevention Week
April 12—CECC/Berman Seminar "Cardiac Drugs"
April 30 (Thurs)—Seminar: Chronic Care & The Elderly: An Update
May 17 (Sun)—CECC Seminar on Arthritis
May 21 (Thurs)—Alumni Association Annual Graduation Banquet
June 21–25—MPhA ANNUAL CONVENTION—SHERATON OCEAN CITY

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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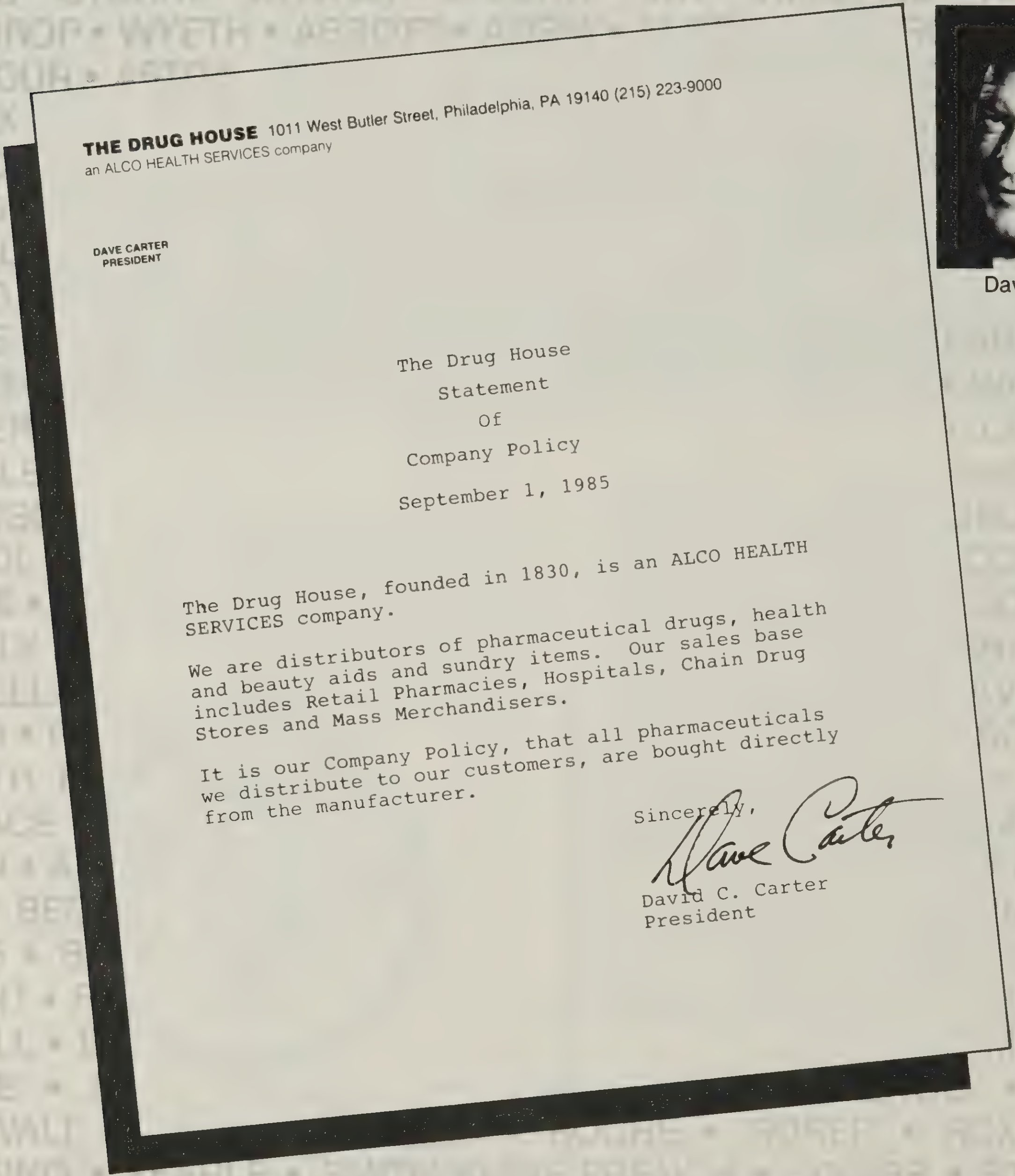

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Advising Consumers on OTC Pinworm Remedies

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— Thomas A. Gossel

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— Jim Dickinson

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— Peter P. Lamy
— Ilene H. Zuckerman

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BENEDICT ARNOLD WAS A PHARMACIST!

No joke—check your encyclopedia. America's best known traitor was a pharmacist before he began his infamous military career. By 1777, Benedict Arnold had risen to the rank of major general. However, he resented what he thought was the tardiness of this promotion. "Ambitious and quick to take offense, Arnold imagined himself slighted by the Congress and victimized by jealous superiors." In 1780, shortly after he was appointed commander of West Point, he sold out to the British. Not one of our finest, I'm afraid.

Recently, our profession has made a few hard-won gains. We have received some very favorable publicity, both nationally and locally, on the subject of dispensing physicians. Additionally, we narrowly escaped a potentially devastating change in reimbursement regulations in the Medicaid Program, and actually came out a little ahead.

As satisfying as these victories are, they, by no means, leave us carefree. There is still much to do—many battles ahead. Let's be sure not to follow the footsteps of our notorious predecessor, Benedict Arnold. We cannot allow ourselves to be bitter over the "tardiness" of our gains nor be "quick to take offense" at our "enemies" or each other. We must stick together for the common good.

George C. Voxakis
PRESIDENT

CONTINUING EDUCATION FOR PHARMACISTS

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Advising Consumers on OTC Pinworm Remedies

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Goals

The goals of this lesson are to:

1. discuss means to prevent and treat pinworms; and
2. present important consumer information about pinworms and the treatment of pinworms.

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Objectives

At the conclusion of this lesson, participants will be able to:

1. discuss the life cycle of pinworms;
2. describe means to prevent and treat pinworm infestations;
3. define the term anthelmintic as it relates to OTC drugs;
4. present the FDA/OTC advisory panel's conclusions on safe and effective anthelmintic drugs; and
5. comment on the future of OTC anthelmintic therapy.

It is enigmatic that pinworm infestation is considered to be self-diagnosable and self-treatable. Yet, there are no OTC products currently available that are both safe and effective for home use.

Gentian violet, long used for self-treatment of pinworms, is now considered by FDA to be potentially unsafe. Pyrantel pamoate (Antiminth®), available for years as a proven, effective pinworm medication on prescription order, has been recommended for OTC status. Its manufacturer has not shifted it at the time of publication of this article.

This article discusses pinworm infestations. It identifies how the problem occurs and why all family members should be treated when any one member is affected. It describes hygienic measures important to eradicate and prevent spread of pinworms. It then discusses the status of OTC drug therapy useful in treating the condition.

Pinworm Infestations

Pinworms (*Enterobiasis*) are variously referred to as threadworms or seat worms. They are among the oldest identified and most prevalent human parasitic infestations. Pinworm eggs have been found in 10,000-year-old fecal remains.

The worm currently affects an estimated 200 million people worldwide. Approximately 40,000,000 victims reside in the United States and Canada. Animals are not part of the pinworm cycle; only humans are infested.

Pinworms are spindle-shaped parasites that spend all but the last few hours of their life within the human alimentary tract. These last hours are spent externally on the anus as they emerge to lay their eggs.

Male worms are 2 to 5 mm in length and rarely seen, probably because of their small size. Females measure 8 to 13 mm (about one-fourth to one-half inch) and are light yellowish-white in color. The term *pinworm* was coined to describe their long, thin, pointed tail that resembles a stickpin.

The worms develop from eggs that reach the gastrointestinal (G.I.) tract. Eggs are fully embryonated and become infective within a few hours after deposition within the G.I. tract. Worms hatch in the proximal small intestine then migrate downward. They may temporarily attach to the wall of the jejunum and upper ileum, but this is rare.

Pinworms copulate in the distal portion of the small intestine. Females then move on to the lower bowel. They attach by their heads to the lining of the cecum, appendix, and adjacent large intestine. In this way, they feed while their eggs develop. Although frequently found impacted in great numbers within the appendix, they rarely cause appendicitis, or other intestinal pathology.

Once a female's eggs have matured, the worm detaches from the intestinal wall and exits through the anus. This normally occurs during the night while the human host is asleep and the muscles are most relaxed. The period between swallowing an egg and emergence of a worm through the anus is approximately one month.

Once they come in contact with air, female pinworms expel their 10,000 to 11,000 "sticky" eggs over the anal and pubic areas. The adult worms then die shortly thereafter. Scratching and rubbing the areas by the human host also helps expel eggs.

Liberated eggs are resistant to damage due to loss of moisture, and can generally survive 2 to 3 weeks at room temperature. Eggs are infrequently laid within the bowel. If this occurs, they are usually immature and not viable.

As stated previously, pinworms only infest humans. They show little preference for males or females; Caucasians, Orientals, or Blacks; or individuals of high or low socioeconomic status. However, they predominately affect children who live in crowded quarters. Once a child becomes infested, the problem then generally becomes a family affair!

As a general rule, pinworm infestation usually occurs by ingesting eggs which reach the mouth on contaminated hands. Eggs may adhere to the fingers or under the fingernails following scratching or handling contaminated undergarments, bed clothes, or other personal items belonging to the infested person. They can also be transmitted by sexual contact, or by touching others who are infested.

Eggs may also be found in food or drink. They are light enough to float in air, so they can be unknowingly inhaled.

Recontamination occasionally occurs from retroinfection. Eggs located in the perianal area may hatch to larvae and then enter the anus. They continue movement upward into the large intestine where they mature. Retroinfection is rare. When it occurs, it is mainly a problem affecting adults.

Self-Diagnosing Pinworm Infestation

Pinworm infestations *per se* are asymptomatic because the worm is a benign parasite. Symptoms occur only when worms exit the anus. The most commonly reported one is anal itching (*pruritus ani*) that may vary from a mild "'tickling'" sensation to intense pain. Itching occurs because of the female worm crawling around, and because of the presence of eggs on the skin. When itching becomes so severe that it interferes with sleep, the victim may complain of restlessness, irritability, and insomnia. The person may display changes in behavior, and be inattentive and generally uncooperative in school and job-related matters, as unrelentless itching continues.

Vaginal itching (*pruritus vulvae*) and/or discharge have occurred in women after the worms have migrated into the vagina. A strong relationship between enterobiasis and urinary tract infection in young girls has likewise been suggested. Ova have been detected in vaginal smears of girls with these infections.

One method of assessing pinworm infestation is to cover the end of a cotton-tipped applicator or tongue depressor with cellophane (i.e., Scotch) tape leaving the sticky side outward. This is then placed against the perianal area to collect eggs that may be present. This collection method alone does not lend to self-diagnosis because pinworm eggs are too small to see with the unaided eye. But eggs can be confirmed under a microscope. Egg collection (if any!) can be done at home. The specimen must then be taken to a physician or laboratory for diagnosis.

Another method is to look for the adult worms exiting the anus. After the child is asleep for approximately one hour, the worms become active. A parent can visually inspect the anus using a flashlight. Female worms may be seen actively moving about depositing eggs on the infested child.

Treatment

The primary goal for therapy of pinworm infestation is to completely eradicate the parasite and its eggs from the entire household. Effective treatment involves instituting drug therapy, and making sure that everyone in the family strictly complies to a hygienic protocol which will minimize the chance that the parasite will be transmitted to others.

All members of the household must be treated in order to eliminate the pinworm infestation. This can be effectively accomplished with anthelmintics. Exceptions to this rule include infants under the age of two, children weighing less than 25 pounds, and pregnant women. The aforementioned persons require medical supervision.

Anthelmintics are drugs that destroy or eliminate intestinal worms. Some drugs that are lethal to pinworms are equally devastating to other worms such as the large roundworm and hookworm. However, since these parasites cause much more serious symptoms and complicating pathology, their presence is considered to be neither self-diagnosable nor self-treatable. A physician should be consulted for either disorder. OTC anthelmintics are indicated *only* for pinworms.

Due to the FDA/OTC advisory panel review of the anthelmintic market, available products will change dramatically. For many years, gentian violet (as Jaynes' P.W. Tablets) was the only agent that could be reliably used at home to eliminate pinworms. But numerous questions have been recently raised about its safety!

The FDA/OTC advisory panel that reviewed anthelmintics concluded that gentian violet was effective. In spite of potential side effects of nausea, vomiting, abdominal pain and diarrhea, and the fact that there are unanswered questions about possible carcinogenic and teratogenic activities, the panel nevertheless considered gentian violet to be generally recognized as safe when properly used.

To offset the probability of gastrointestinal side effects, the panel recommended to FDA that OTC gentian violet products be available only as enteric-coated tablets. In this dosage form, panel members felt that by delaying drug release until it reached the small intestine, the occurrence and intensity of G.I. tract irritation would be reduced and patient compliance enhanced.

After carefully reviewing the panel's report, FDA disagreed with this recommendation. The agency stated that in its opinion, the health benefit was far outweighed by potentially serious risks.

When reporting this in 1980, FDA asked for public comments on its de-

TABLE 1

Reasons Why FDA Suggested That Gentian Violet Be Removed From OTC Pinworm Remedies

- High incidence of GI adverse effects, especially in children
- Potential toxicity
- Scarcity of acute toxicity data
- Low patient compliance
- Relatively low efficacy
- Availability of superior anthelmintic (pyrantel pamoate)

cision. By the end of the prescribed two years waiting period, no comments had been received. So FDA announced its intention to remove gentian violet from the OTC marketplace.

Since there is no overt consumer danger present, gentian violet-containing pinworm remedies can continue to be marketed until FDA publishes its Final Monograph in the Federal Register. The major reasons why FDA suggested gentian violet be removed from the market are listed in Table 1.

Pyrantel Pamoate. This drug represents an interesting situation in that it is a prescription-only drug that has been recommended for shift to OTC status. Its safety and effectiveness in animals led to its use as a prescription item in treating a variety of human worm infestations.

When the OTC advisory panel concluded its studies, it reported that as of 1980, more than 100 million people worldwide had taken pyrantel pamoate without serious complications. Pyrantel pamoate had been one of the drugs of choice (along with mebendazole — Vermox®) against pinworms for over a decade. Few toxic reactions have been reported since the drug was introduced into human medicine in 1972. Retrospectively, it is difficult to pinpoint pyrantel pamoate as the cause of reported ototoxicity, optic neuritis, mental confusion and hallucinations occasionally observed in patients taking it concurrently with other drugs.

Additionally, long-term studies in laboratory animals have failed to attribute any morphologic changes to the drug. There have been no effects on fertility, reproduction, organ development or lactation.

One potential problem singled out by the panel and reiterated by FDA is that there is documented evidence of a transient elevation of the hepatic enzyme serum glutamic oxalacetic transaminase (SGOT) in a small percentage of children taking the drug. In all instances, SGOT levels returned to normal after therapy was discontinued. There is no confirmed liver damage associated with the use of pyrantel pamoate. Adverse effects reported for pyrantel pamoate are listed in Table 2

These effects are not considered to contribute to a significant safety question in most patients. FDA nevertheless will require a warning statement on the labeling of OTC pyrantel pamoate products advising against unsupervised use in patients with liver disease. Other statements are presented in Table 3.

A major reason for the high safety profile of pyrantel pamoate is that it is not appreciably absorbed. It is virtually insoluble in water. Approximately 85 percent of each dose is excreted unchanged in the feces. The remainder appears in the urine as intact or partially metabolized drug.

Action and Dosing. Pyrantel pamoate is a depolarizing neuromuscular blocking agent. It acts in a manner similar to succinylcholine. The drug causes intense nicotinic stimulation of neuromuscular junctions, and also inhibits the enzyme cholinesterase. In other words, worms initially contract, but continued drug action soon results in a spastic paralysis. The worm's contractile hold on the intestinal wall is lessened. It falls away and is expelled.

The usual single dose of pyrantel pamoate suspension is 5 mg/pound of body weight, not to exceed 1 gm. The same dosage regimen applies to both children and adults. Pyrantel pamoate can be taken any time of day, with meals or on an empty stomach, and straight-up or with juice, milk or other beverage.

TABLE 2

Adverse Effects Reported For Pyrantel Pamoate

Gastrointestinal (most common):
  Nausea, vomiting, abdominal cramping, diarrhea
Anorexia
Headache
Dizziness
Drowsiness
Restlessness
Irritability
Insomnia
Rash
Transient elevation in SGOT levels

TABLE 3

Warnings For Labeling of Pyrantel Pamoate When It Becomes OTC

- If upset stomach, diarrhea, nausea or vomiting occurs with the use of this product, consult a doctor.
- If you have liver disease, do not take this product unless directed by a doctor.
- If you are pregnant, do not take this product unless you have pinworms yourself and are directed to take it by your doctor.

Other Potential OTC Anthelmintics?

Piperazine Citrate. The FDA/OTC advisory panel reviewed one other prescription anthelmintic, piperazine citrate, for possible shift to OTC status. After studying the data, the panel concluded (and FDA agreed) that while it is generally safe, piperazine citrate is potentially too toxic for unsupervised use.

While they do not occur in many patients taking it, the drug has potential for causing neurotoxic side effects. These include mental confusion, uncoordination, epileptic seizures and somnolence to the extent that the benefit-to-risk ratio is inappropriate for OTC availablility. Therefore, piperazine citrate will continue to require a prescription for use.

The panel did not investigate other pinworm remedies. It did urge manufacturers to review clinical data on their products with an eye toward switching them from prescription-only to OTC status when appropriate. However, there is no indication that another anthelmintic will be marketed OTC in the near future.

Patient Advice and Summary

Consumers purchasing an OTC anthelmintic remedy should understand the importance of proper dosing and adherence to directions. They should be made familiar with how the infection is transmitted and how it is best avoided.

Pinworms can be suspected whenever there is persistent rectal itching that cannot otherwise be explained. Important information for consumers about pinworm control is presented in Table 4.

TABLE 4

Consumer Information On Pinworms

- Wash hands and under fingernails carefully before eating or drinking; repeat after each use of the toilet.
- Keep fingernails short and well trimmed.
- Keep fingers away from the mouth and nose.
- Pay strict attention to complete personal hygiene and household cleanliness; clean bathroom fixtures and vacuum carpets daily.
- Carefully wash and fold (without shaking) all sleep clothing, undergarments, bed linens, towels and washcloths each day. Soak these in ammonia water (one cupful/5 gallons cold water) for one hour if they cannot be laundered each day.
- Children should shower or take stand-up baths daily, preferably in the morning, and thoroughly wash and rinse the anal and pubic areas.

Patient Aid

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

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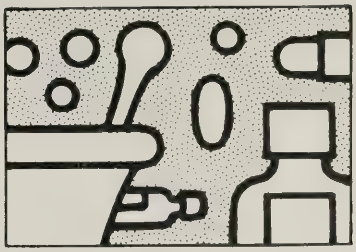
Things You Should Know FOR YOUR GOOD HEALTH



Let's Fight Drug Abuse Together

In recent years, drug abuse has been receiving increased attention by health care professionals and the general public. Nearly 70 percent of young adults between the ages of 18 to 25 have abused drugs of various forms. Alcohol is the most commonly abused drug in the United States, followed closely by marijuana.

Here is a short drug quiz for you to test your knowledge. The correct answers are presented at the end of the quiz. You may find it informative and learn some facts about drug abuse.

1. Stopping drug abuse before it starts is called
   a. prevention.
   b. withdrawal.
   c. tolerance.
   d. education.
2. The most commonly abused drug in the United States is
   a. marijuana.
   b. alcohol.
   c. cocaine.
   d. PCP (Angel Dust).
3. Which age group has the highest percentage of illicit drug use?
   a. 10-17
   b. 18-25
   c. 26-35
   d. 36-60
4. What sobers up a drunk person?
   a. a cold shower
   b. black coffee
   c. a traffic ticket
   d. time
   e. walking
5. How long does marijuana stay in the body after smoking?
   a. one hour
   b. 12 hours
   c. one day
   d. up to a month
6. Which of the following should **never** be mixed with alcohol?
   a. amphetamines
   b. sedatives
   c. cocaine
   d. cigarettes
7. Who in the community may I ask about drugs?
   a. doctor
   b. teacher
   c. pharmacist
   d. all of the above
8. The fastest growing abused drug today is considered to be
   a. marijuana.
   b. Angel Dust.
   c. alcohol.
   d. cocaine.
9. Which drug causes the most unpredictable reactions?
   a. PCP
   b. heroin
   c. alcohol
   d. marijuana
10. The use of drugs during pregnancy
    a. should be limited to tobacco and alcohol.
    b. may be harmful to the unborn child.
    c. should cease at 26 weeks.
11. One 12 oz. can of beer contains the same amount of alcohol as
    a. a half pint of whiskey.
    b. a glass of wine.
    c. 1-1/2 oz. of whisky.

Answers: 1-A, 2-B, 3-B, 4-D, 5-D, 6-B, 7-D, 8-D, 9-A, 10-B, 11-C.

If you would like more details about any of the above questions, **Ask Your Pharmacist.** Your pharmacist is a medication expert and drug abuse is a serious concern to all.

(Special thanks to McNeil Pharmaceutical for the above information).

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Please see next page for brief summary.

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Brief Summary

ISOPTIN® SR
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CONTRAINDICATIONS: 1) Severe left ventricular dysfunction (see WARNINGS), 2) Hypotension (less than 90 mmHg systolic pressure) or cardiogenic shock, 3) Sick sinus syndrome or 2nd or 3rd degree AV block (except in patients with a functioning artificial ventricular pacemaker).

WARNINGS: Heart Failure: ISOPTIN should be avoided in patients with severe left ventricular dysfunction (see DRUG INTERACTIONS). Patients with milder ventricular dysfunction should, if possible, be controlled before verapamil treatment. Hypotension: ISOPTIN (verapamil HCl) may produce occasional symptomatic hypotension. Elevated Liver Enzymes: Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Periodic monitoring of liver function in patients receiving verapamil is therefore prudent. Accessory Bypass Tract (Wolff-Parkinson-White): Patients with paroxysmal and/or chronic atrial flutter or atrial fibrillation and a coexisting accessory AV pathway have developed increased antegrade conduction across the accessory pathway producing a very rapid ventricular response or ventricular fibrillation after receiving intravenous verapamil. While this has not been reported with oral verapamil, it should be considered a potential risk. Treatment is usually D.C.-cardioversion. Atrioventricular Block: The effect of verapamil on AV conduction and the SA node may cause asymptomatic 1st degree AV block and transient bradycardia. Higher degrees of AV block, while infrequent (0.8%), may require a reduction in dosage or, in rare instances, discontinuation of verapamil HCl. Patients with Hypertrophic Cardiomyopathy (IHSS): Although verapamil has been used in the therapy of patients with IHSS, severe cardiovascular decompensation and death have been noted in this patient population.

PRECAUTIONS: Impaired Hepatic or Renal Function: Verapamil is highly metabolized by the liver with about 70% of an administered dose excreted in the urine. In patients with impaired hepatic or renal function verapamil should be administered cautiously and the patients monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacological effects (see OVERDOSAGE).

Drug Interactions: Beta Blockers: Concomitant use of ISOPTIN and oral beta-adrenergic blocking agents may be beneficial in certain patients with chronic stable angina or hypertension, but available information is not sufficient to predict with confidence the effects of concurrent treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities. Digitalis: Clinical use of verapamil in digitalized patients has shown the combination to be well tolerated if digoxin doses are properly adjusted. However, chronic verapamil treatment increases serum digoxin levels by 50 to 75% during the first week of therapy and this can result in digitalis toxicity. Upon discontinuation of ISOPTIN (verapamil HCl), the patient should be reassessed to avoid underdigitalization. Antihypertensive Agents: Verapamil administered concomitantly with oral antihypertensive agents (e.g., vasodilators, angiotensin-converting enzyme inhibitors, diuretics, beta blockers, prazosin) will usually have an additive effect on lowering blood pressure. Patients receiving these combinations should be appropriately monitored. Disopyramide: Disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration. Quinidine: In patients with hypertrophic cardiomyopathy (IHSS), concomitant use of verapamil and quinidine resulted in significant hypotension. There has been a report of increased quinidine levels during verapamil therapy. Nitrates: The pharmacologic profile of verapamil and nitrates as well as clinical experience suggest beneficial interactions. Cimetidine: Two clinical trials have shown a lack of significant verapamil interaction with cimetidine. A third study showed cimetidine reduced verapamil clearance and increased elimination to 1/2. Anesthetic Agents: Verapamil may potentiate the activity of neuromuscular blocking agents and inhalation anesthetics. Carbamazepine: Verapamil may increase carbamazepine concentrations during combined therapy. Rifampin: Therapy with rifampin may markedly reduce oral verapamil bioavailability. Lithium: Verapamil may lower lithium levels in patient on chronic oral lithium therapy. Carcinogenesis, Mutagenesis, Impairment of Fertility: There was no evidence of a carcinogenic potential of verapamil administered to rats for two years. Verapamil was not mutagenic in the Ames test. Studies in female rats did not show impaired fertility. Effects on male fertility have not been determined. Pregnancy (Category C): There are no adequate and well-controlled studies in pregnant women. ISOPTIN crosses the placental barrier and can be detected in umbilical vein blood at delivery. This drug should be used during pregnancy, labor, and delivery, only if clearly needed. Nursing Mothers: ISOPTIN is excreted in human milk, therefore, nursing should be discontinued while verapamil is administered. Pediatric Use: Safety and efficacy of ISOPTIN in children below the age of 18 years have not been established.

ADVERSE REACTIONS: Constipation 8.4%, dizziness 3.5%, nausea 2.7%, hypotension 2.5%, edema 2.1%, headache 1.9%, CHF/pulmonary edema 1.8%, fatigue 1.7%, bradycardia 1.4%, 3° AV block 0.8%, flushing 0.1%, elevated liver enzymes (see WARNINGS). The following reactions, reported in less than 1.0% of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain; they are mentioned to alert the physician to a possible relationship: angina pectoris, arthralgia and rash, AV block, blurred vision, cerebrovascular accident, chest pain, claudication, confusion, diarrhea, dry mouth, dyspnea, ecchymosis or bruising, equilibrium disorders, exanthema, gastrointestinal distress, gingival hyperplasia, gynecomastia, hair loss, hyperkeratosis, impotence, increased urination, insomnia, macules, muscle cramps, myocardial infarction, palpitations, paresthesia, psychotic symptoms, purpura (vasculitis), shakiness, somnolence, spotty menstruation, sweating, syncope, urticaria. Treatment of Acute Cardiovascular Adverse Reactions: Whenever severe hypotension or complete AV block occur following oral administration of verapamil, the appropriate emergency measures should be applied immediately, e.g., intravenously administered isoproterenol HCl, levarterenol bitartrate, atropine (all in the usual doses), or calcium gluconate (10% solution). If further support is necessary, inotropic agents (dopamine or dobutamine) may be administered. Actual treatment and dosage should depend on the severity and the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE: Treatment of overdosage should be supportive. Beta-adrenergic stimulation or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been used effectively in treatment of deliberate overdosage with verapamil. Clinically significant hypotensive reactions or fixed high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including cardiopulmonary resuscitation.

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"TIMELY TOPICS"

A regular monthly feature sponsored by the Parke-Davis Center for the Education of the Elderly and the Elder-Health Program, University of Maryland School of Pharmacy. At the conclusion of each series, a sample "Elder-Ed" talk for presentation to the community will be outlined.

PHARMACOLOGIC CONSIDERATION IN THE TREATMENT OF ALZHEIMER'S DISEASE

Part III

by Peter P. Lamy, PhD
Ilene H. Zuckerman, PharmD

Drugs Used for AD Patients with Intercurrent Problems

Behavioral Problems: Behavioral disturbances, such as restlessness, uncooperativeness, wandering, and assaultiveness are often associated with dementia. AD patients often are also anxious and fearful, suspicious and even paranoic. They commonly present with aggressive and agitated behavior.

It is important to realize that behavioral disturbances in dementia may be episodic and, therefore, management of disturbances with drugs should match the episodic nature of the problem and should not be protracted.

Behavioral symptoms that are probably most responsive to drugs are suspiciousness, hallucinations, sleeplessness, and agitated behavior, such as excitement, hostility, belligerence, or emotional lability. Repetitive and bothersome behavior, such as pacing or calling out is usually less responsive to drug management.

The antipsychotics are most often used. They are also called "neuroleptics", since they can produce adverse neurologic effects resembling parkinsonism.

Antipsychotics are usually compared in terms of relative potency (Table VI):

TABLE 6
Relative Potency of Antipsychotics

	Chlorpromazine equivalence (CPZ-E)
Chlorpromazine HCl	1
Thioridazine HCl	1
Perphenazine	10
Loxapine HCl	10
Molindone HCl	10
Trifluoperazine HCl	20
Thiothixene	20
Haloperidol	50
Fluphenazine HCl	50

Presented at the meeting of the Health and Education Council "Meeting the Challenge of Alzheimer's Disease and Related Disorders", Baltimore, Maryland, 1986

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They are commonly divided into two classes, reflecting their potency, i.e., the low-potency drugs (chlorpromazine, thioridazine) and the high-potency ones (haloperidol, fluphenazine, trifluoperazine). In equipotent doses, the high-potency drugs have a greater incidence of etrapyramidal side effects (e.g. Parkinsonism). The low-potency drugs are more sedating, cause more postural hypotension, and have a greater anticholinergic effect. The predominant side effects of higher potency drugs are more easily manageable with medications and may be less troublesome in most patients. Medication choice, therefore, may be based on differences in side effects that the patient may be able to tolerate. In individual patients, idiosyncracies may occur, and patient management is important in finding the most effective choice of drug.

Antipsychotics may induce tardive dyskinesia (TD) in patients who have been taking one or a central dopamine receptor-blocking drug for a year or more. Other risk factors include old age, brain damage, and schizophrenia. Thus, elderly patients may be at a particularly high risk for developing TD with subsequent severe movement and feeding problems. At present, no safe and effective treatment for TD has emerged and, thus, there are significant benefits to be gained by addressing this issue and the need to use these drugs with the patient (if possible) and the patient's family before instituting treatment.

When TD symptoms first occur, the dose of the drug should be lowered to prevent irreversible symptoms from developing. "Drug holidays" which allow dopamine receptors to recover, have not proved to be very effective. Anticholinergic, anti-Parkinson drugs, which can mask the symptoms of TD, should not routinely be given to prevent the parkinsonian effects of the antipsychotics. Furthermore, it is generally believed that these drugs do not act prophylactically in elderly patients.

Antipsychotics should be used only when necessary and for as short period of time as possible for still another reason. Elderly patients commonly exhibit altered pharmacokinetic and pharmacodynamic parameters of drug action. Pharmacokinetically, there is likely to be an altered ratio of lean body weight to fatty tissue, with an increase in the latter and a decrease in the former, even in patients who have not gained weight. There may be decreased hepatic metabolism and, most likely, there will be decreased renal clearance. The brain may be more sensitive to the CNS effects of these drugs. Therefore, it has been recommended that psychotropics be started in the elderly with one-third to one-half the standard adult dose. The starting dose may be lowered further in patients with brain damage. The dose should then be adjusted as necessary over time.

Low doses of antipsychotics may be effective in managing behavioral problems of AD patients, but only in a minority of patients (up to 40% in some studies). Indeed, 10% of patients may worsen when antipsychotic drug use is instituted. Low dose thioridazine, in several studies, has been shown to be able to reduce agitation, anxiety, irritability, and hostility. Thioridazine (approx. 100 mg/day) and haloperidol (2 mg/day) were effective in controlling these symptoms in 40% of demented nursing home patients. On the other hand, haloperidol patients, in some studies, were significantly confused and motor retarded. Drowsiness and unsteadiness occurred, and extrapyramidal symptoms were common in one study group receiving haloperidol. Patients most likely to respond to antipsychotic treatment were those with the most severe behavioral symptoms before treatment. On the other hand, neuroleptics do not appear to be helpful for impaired memory, poor self-care, indifference, and unsociability. In fact, the side effects of these drugs may worsen these symptoms.

Since anxiety often accompanies dementia, benzodiazepines have been tried and shorter-acting benzodiazepines may, at times, demonstrate some benefit. Although several studies have consistently shown thioridazine to be favored in anxious, agitated dementia patients, oxazepam (20 to 30 mg/day) has also been shown to be effective in most patients. However, up to 30% of these patients were oversedated. Other benzodiazepines have been tried and have been variously effective/ineffective. In short, sedation, confusion, memory impairment (Table VII) and ataxia are commonly reported side effects in older patients when benzodiazepines and use, but they may be useful in less severely agitated patients in whom anxiety or sleep disturbance is prominent.

TABLE 7
Anti-Anxiety Agents and Memory Impairment in Elderly

Drug	Memory Impairment
Short-acting	
Alprazolam	+ +
Oxazepam	+
Intermediate	
Lorazepam	+ + +
Long-acting	
Diazepam	+ +
Chlorazepate dipotassium	+

Other drugs that have been tried in the management of behavioral problems of elderly AD patients include lithium (it may cause cognitive impairment and confusional states), propranolol (it may cause hypotension and bradycardia), carbamazepine, and antihistaminic drugs. The latter, having anticholinergic properties, can cause confusion, constipation, urinary retention, circulatory and respiratory depression, and delirium.

Depression: Depression is often mistaken for dementia. Both are common as people age. They may often co-exist. The time profile for both is similar. To differentiate, a history is crucial. In depressive pseudodementia, there is often a personal or family history of depression. Depressed patients often and readily complain about loss of memory, a complaint that is rare in AD patients. Vegetative symptoms of depression in demented patients would include loss of appetite, disturbance of sleep, easy fatigability, psychomotor agitation or retardation, and loss of interest. One also needs to differentiate between agitation and anxiety. Agitation is an irritable, hyperactive state, more associated with depression or dementia. It is usually worsened by the use of benzodiazepines, but helped by antipsychotics (thioridazine seems to be most effective). Anxiety is similar to fear. It is associated with stress and physical symptoms, such as diaphoresis, tachycardia, and conscious distress. As outlined, it may be helped by benzodiazepines or neuroleptics.

All of the antidepressants have anticholinergic properties which, in the elderly, can cause considerable problems. Antidepressants also should be used episodically, and, if they are to be withdrawn, the dose should be gradually tapered over 14 days. This will avoid possible withdrawal symptoms, such as nausea, vomiting, malaise, muscular aches, sleep disturbances, movement disorders, and paradoxic excitation. Psychiatric withdrawal symptoms must be carefully differentiated from depressive relapse: withdrawal symptoms usually begin within two weeks, while a depressive relapse would tend to begin within three to 15 weeks and continue to worsen.

Sleep Problems: If elderly AD patients present with sleep disturbances, one needs first to rule out drug effects. Bedtime doses of amantadine can cause insomnia. If propranolol is given at bedtime, patients may complain that vivid, unpleasant dreams disturb their sleep. Similarly, if a total daily dose of an antipsychotic or antidepressant is given to these patients at bedtime, night terrors and anxiety dreams, as well as cardiovascular problems, may result.

It is generally agreed that sedatives/hypnotics should not be used in demented patients (Table VIII) nor be given for a prolonged period of time. Sedating neuroleptics should not be used for non-psychotic or non-agitated patients for sleep problems, and antidepressants should not be used for their sedating effect only.

TABLE 8
Sedatives/Hypnotics and Memory Impairment

Drug	Memory Impairment
Benzodiazepines	
Short-acting	
Triazolam	+ + + +
Oxazepam	+
Intermediate	
Temazepam	+ +
Lorazepam	+ + +
Long-acting	
Flurazepam	+ +
Non-benzodiazepines	
Chloral hydrate	+
Diphenhydramine HCl	+ +

Demented patients who are sundowning usually respond to low-dose, sedating neuroleptics. Some practitioners prefer thioridazine (25 to 100 mg/h.s.). Thioridazine appears to have a low risk of causing tardive dyskinesia and, at this low dose, cardiovascular and anticholinergic side effects are usually small. Some patients may respond well to a bedtime dose of 25 to 50 mg. of diphenhydramine HCl. However, if patients are treated with sedatives/hypnotics, they usually respond paradoxically and become agitated.

SUMMARY

Drug management of elderly AD patients is difficult. No drug has as yet emerged which is effective. Drugs needed to manage intercurrent problems are available, but they are effective only in a minority of patients and, in many patients, their side effects can cause considerable problems.

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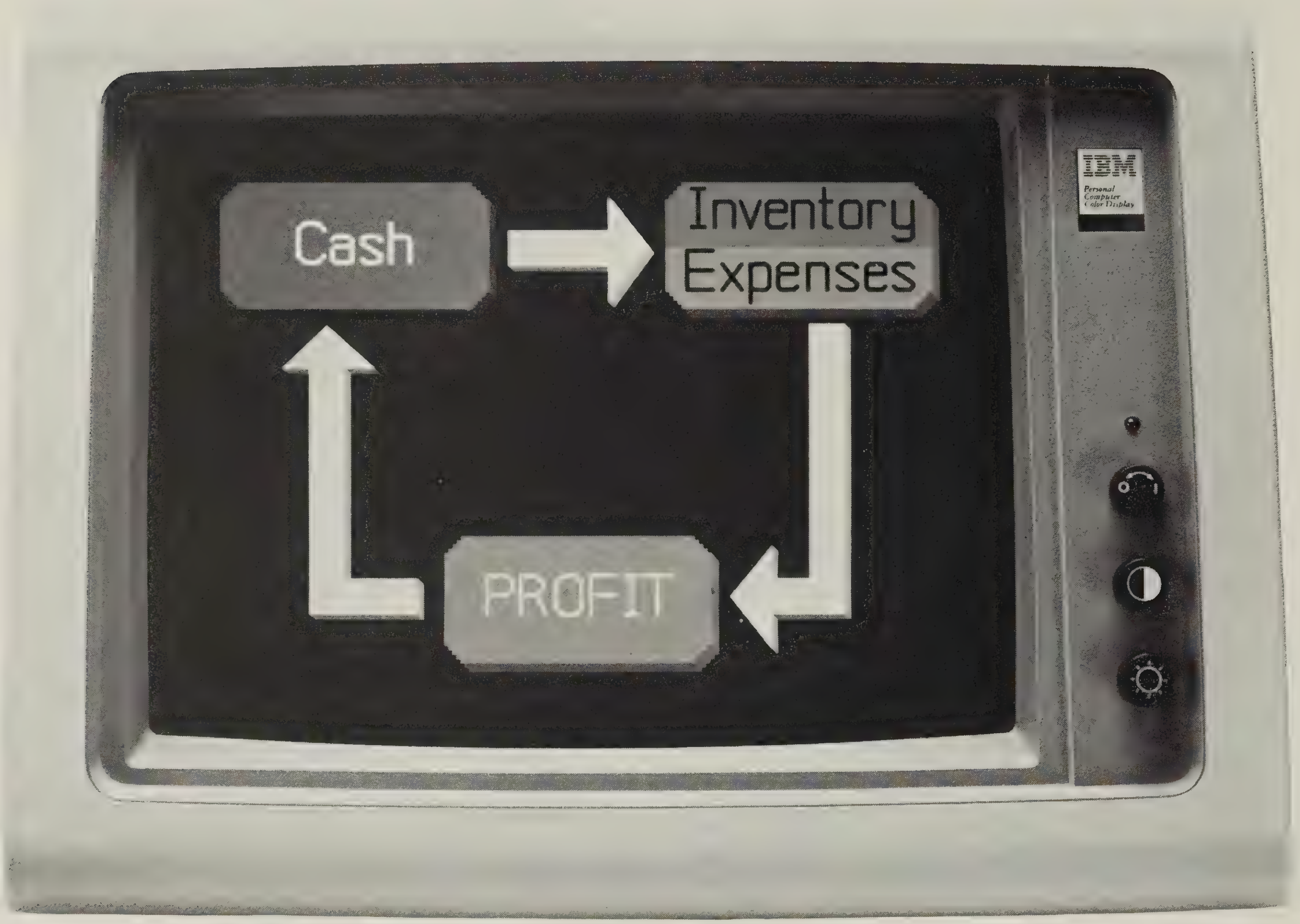

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Case Study: Losing to the Chains

by Jim Dickinson

How does a firmly-established independent pharmacy lose a reliable and active, chronic patient to a drug chain in a prescription market that most experts agree is moving from price to service as its primary denominator?

This question goes right to the root of the survivability of independent pharmacy, and to the effectiveness of the PSAO (Pharmacy Services Administrative Organization) movement now sweeping the country. Because of this, the following case study (disguised to protect your columnist from lawyers but nonetheless based on fact) is importantly instructive.

Paul M, 46, is a self-employed businessman who's a well-stabilized chronic patient in a community that has three independent pharmacies and three chain drug stores. His drug bill runs about $200 a month, at the largest of the three independents, which has had his business for years.

Because he's well-stabilized, and because his life is orderly, the pharmacy's services have not concerned Paul. It has never bothered him, for instance, that the pharmacy is never open Sundays, unlike Thrifty Drug, Rite Aid and SupeRx.

Paul likes the convenience of charging his hefty drug purchases, especially when slow insurance reimbursements tie up his cashflow and cause him to run his account past 30 days.

And he likes the pharmacy itself. Although it does a heavy volume, it has managed to keep a small and personal atmosphere; in short, it looks like he thinks a pharmacy should look.

Emergency service, like Sunday service, had never been important to Paul. And that's the focal point of this case study—suddenly, both became very important to him.

Paul's small business began to expand, and the orderliness of his life—and of his medication schedule—changed.

One Friday night, as he was packing for a pre-dawn Saturday departure on a week-long business trip, he realized that one of his medicines would run out on Monday.

That's when he discovered that his independent pharmacy did not have an after-hours number. Not to worry, though—he'd leave a note under the pharmacy door with a completed Federal Express label on his way out of town—the pharmacist could ship it across country the next day, and it would be at his hotel bright and early Monday morning.

Paul's weekend passed in travel and business calls. So did an entire Monday—without his medication. Alarmed, he called his pharmacy during a break in a business meeting, to learn that the medication was not shipped until that very morning.

''But I need it *now!*''

''I sent it as soon as I saw your note,'' the pharmacist said, defensively.

''But I put that note under your door on Friday night—why didn't you send it Saturday? I even made out the Federal Express label for you, on my own account.''

''I don't know. The fellow who was here Saturday is off for three days. I sent it as soon as I saw your note.''

Furious and frightened, Paul broke away from the meeting and went to the nearest pharmacy, which happened to be a Longs drug chain. He explained his plight to the pharmacy, showing the empty vial, and was dispensed enough to last him through his crisis.

That made Paul think about the different kinds of pharmacies, and what they do. Chains in his home town, he realized, don't close at 6:00 PM and all day Sundays, like his independent did. And the chain pharmacist who helped him as a total stranger was at least as personable and understanding as his own pharmacist.

Paul suddenly realized how vulnerable his independent pharmacy made him, lacking an after-hours emergency service when his expanding business would doubtless send him out of town at short notice again and again, more and more often. At the very least, he felt, his pharmacist should have had an answering service. The convenience of a charge account suddenly paled next to after-hours service.

It's not important to this case study to record what Paul did about his problem. What is important is the realization that his problem is symptomatic of a profound change in society's thinking about health care. As more and more people begin to work for themselves—and to self-insure, in the case of employers—the simplistic notion that price/convenience are everything yields to notions such as cost-effectiveness, drug utilization reviews, emergency service for increasingly mobile patients, and patient counseling.

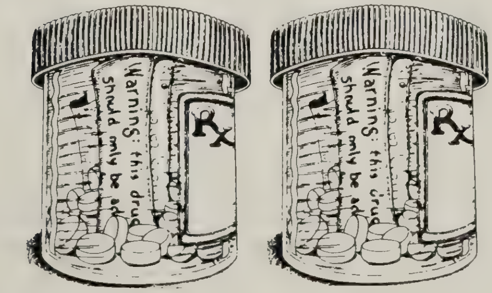
This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

The "S" in PSAO is the key, and it's strategically placed exactly where it belongs—right beside "Pharmacy." Paul paid twice for the same drug, and used Federal Express at additional cost to himself, simply because his pharmacy could not respond to an emergency situation before he left town; in short, it could not be as helpful as a later-closing chain drugstore would have been.

"Service" isn't a big word. It can mean different things to different people. It's over-promoted and under-fulfilled. But it's what health care buyers want. The pharmacy—chain or independent—that fails to deliver it will likely lose out to one that does.

MPhA STAFF EXPANDS

Jean Hoffman joins MPhA staff as Drug Utilization Review Director. Jean is a 1981 graduate of the University of Wisconsin School of Pharmacy and has worked in various practice settings over the past 5 years. Currently she is serving on APhA's Policy Committee on Professional Affairs and seeking a Master's degree in General Administration from the University of Maryland.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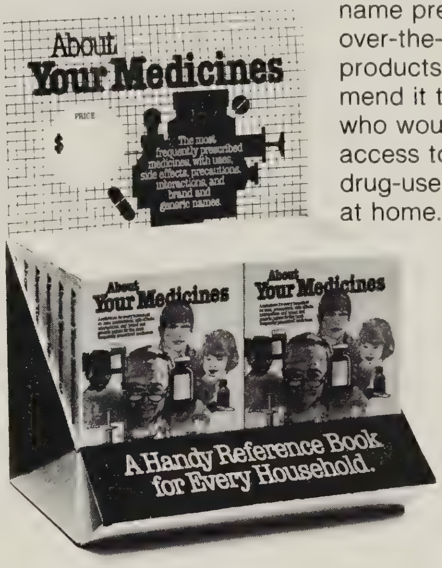
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Toward a Biological Understanding of Central Nervous System Disorders

Nature and nurture, heredity and environment—what is the mysterious blend that shapes the development of human behavior?

Science has come a long way in the past 100 years—far enough to suggest Sigmund Freud may have been correct when he predicted that biology, not psychology, might one day unveil the mysteries of our behavior.

While human nature still cannot be reduced entirely to molecules (and probably never will be), the explosive growth of new information in neuroscience and psychiatry has gone a long way toward fulfilling Freud's century-old prognostication. Recent developments in this field have led to a clearer understanding of mania, depression, schizophrenia and Alzheimer's disease. The key development has been the evolution of brain receptor research.

Before reviewing specific contributions of receptor technology toward understanding of psychiatric disorders, it may prove useful to review current thinking about the role of receptors in central nervous system (CNS) biology.

Basic Framework of the Central Nervous System—The Neural Network

The impact that the biological sciences have had on psychiatry can be traced to new information uncovered about the subtle workings of the brain.

As scientists have unraveled the detailed structure and intricate function of the central nervous system, many advances have taken place. Perhaps the single most important discovery is that the nervous system's basic framework is a network of *neurons*, or nerve cells, the building blocks of the central nervous system. The neuron provides a variety of avenues for altering brain function. A highly specialized cell, it carries signals across long and short distances, forming specific connections with other neurons.

Neurotransmitters carry chemical messages across synapses—minute spaces between nerve cells. By applying knowledge gained over the past 40 years about the nervous system, scientists are able to chemically alter the function of the neuron, using new drugs in the treatment of diseases such as schizophrenia, mania and depression.

Once released, some neurotransmitter molecules flow across the synapse and bind by a precise "hand-in-glove" fit to specific *receptor sites*. Each kind of neurotransmitter has a specific type of receptor to which it binds, just as puzzle pieces fit together in a specific fashion. These various binding relationships in neurotransmission constitute a remarkably versatile relay system with many different circuit breakers.

This intricate relay process is duplicated simultaneously in billions of neurons and synapses throughout the brain and the nervous system, forming the medium through which we experience the multitude of external and internal sensations that bombard us every hour.

In the last two decades, dozens of possible neurotransmitters and receptors have been identified in brain tissue.

Receptors located in the brain and throughout the body recognize and bind specific neurotransmitters, hormones or drugs. Adrenaline acting on beta-adrenergic receptors, for example, stimulates the heart rate and sets in motion a number of other physiological responses. In like fashion, receptor-transmitter interaction directly influences mood, appetite, blood pressure, coordination, pain perception and a multitude of other functions.

Some drugs bind to a receptor and fail to trigger a response. These drugs (called *antagonists*) block the action of certain other neurotransmitters, hormones or drugs (called *agonists*) that bind to the same receptor and do trigger a response.

Receptors Are Regulated by a "Feedback" Mechanism

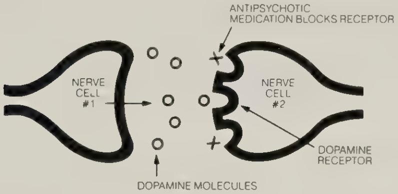
The normal, healthy neuron is a superbly balanced creation of nature, replete with mechanisms that maintain it in a steady state. If, for instance, excess neurotransmitter is released because of the action of a stimulant drug (such as amphetamine) or because of a flow in body chemistry, this excess could eventually reduce the number of available receptors or diminish their ability to bind the transmitter molecules, and thus bring function back toward normal. This finely tuned, adaptive response is called *receptor down regulation.* (See Figure #1—How Brain Receptors Adapt to the Body's Changing Internal Environment.)

According to one theory, some patients suffering from clinical depression may produce inadequate amounts of certain neurotransmitters. Consistent with such a theory, many drugs used in the treatment of de-

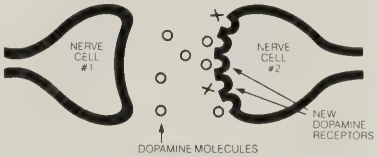
FIGURE 1: **HOW BRAIN RECEPTORS ADAPT TO THE BODY'S CHANGING INTERNAL ENVIRONMENT**

Up Regulation and Down Regulation of Receptors Are the Body's Attempts to Maintain Equilibrium

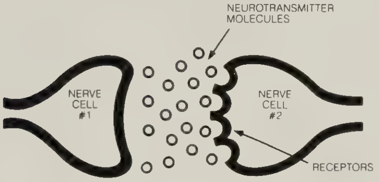
Example #1.
Schizophrenia
Antipsychotic medications block dopamine receptors, reducing the binding of dopamine (from nerve cell #1) to receptors on nerve cell #2.



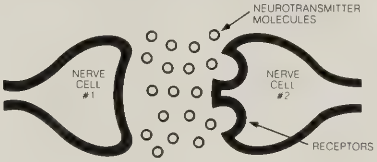
Response: Up Regulation
Change in dopamine receptors produces either an increase in their ability to bind dopamine and/or an increase in the number of receptors on nerve cell #2. This process is called receptor up regulation



Example #2:
Depression
Antidepressant medications increase available neurotransmitter molecules causing excess neurotransmitter to bind to nerve cell #2.



Response: Down Regulation
Change in specific receptors produces either a decrease in their ability to bind certain neurotransmitters and/or decrease in the number of receptors on nerve cell #2. This process is called receptor down regulation.



Nerve Cell #1 – site of neurotransmitter synthesis
Nerve Cell #2 – contains receptor sites that bind neurotransmitters.

ILLUSTRATION – THE UPJOHN COMPANY

pression increase neurotransmitter levels and consequently produce receptor down regulation. However, no one knows for sure whether the therapeutic effects of the antidepressants are due to increased neurotransmitter levels, receptor down regulation or some as yet unidentified mechanism.

"Receptor down regulation may have something to do with the mechanism of the therapeutic action of the antidepressant drugs," says Solomon Snyder, M.D., director, department of neuroscience, at the Johns Hopkins University School of Medicine in Baltimore. "This idea has been advanced as a potential explanation for the delay of several weeks often required for antidepressant action. However, it is also possible that the greater amount of neurotransmitter acting on receptors is solely responsible for relieving depression. It may just take a while for this process to take effect."

Drugs with receptor antagonist action (such as the antipsychotic medications that block dopamine receptors) ultimately produce just the opposite effect—*receptor up regulation,* an increase in the number of receptors or an increase in their ability to bind neurotransmitters.

Turning Off the Signal Is as Important as Turning It On

Neurotransmitter signals must also be terminated or life would be an impossible series of unending seizures and uncoordinated movements.

Some neurotransmitters are inactivated by one or more specific "destructive" enzymes. The *catecholamines* (dopamine, epinephrine and norepinephrine), as well as some other neurotransmitters, are destroyed by such an enzyme, monoamine oxidase (MAO). *MAO inhibitors,* among them phenelzine sulfate (Nardil, Parke-Davis), raise a depressed patient's lowered catecholamine levels and thereby help life depression—through the mechanism by which this happens is not fully understood.

In addition, the actions of the catecholamine neurotransmitters (and possible other types as well) can be brought to an end by a mechanism that pumps neurotransmitter molecules back into the neurons that secreted them. The bulk of released neurotransmitter is inactivated by this process, and some is repackaged for later use. In order to take advantage of this process, *tricyclic antidepressants* (*TCAs*) such as imipramine hydrochloride (Tofranil, Geigy) inhibit this pump system, thereby prolonging the action of available neurotransmitter and relieving depression.

Understanding Mania, Depression, Schizophrenia and Alzheimer's Disease

The biological revolution in psychiatry has had a far-reaching effect on the perception of mental illness and its treatment. As neurobiological advances are made and the connections between biology and behavior are established, psychiatrists hope to gain access to newer and more specific drugs to treat illnesses once considered hopeless.

"First, medical science discovered and used psychiatric medicines. Now, we're figuring out how they work," says Dr. Snyder. Overall, there appears to be a strong connection between neurotransmitter systems, mental function and psychiatric drugs.

"As in other areas of medicine, understanding basic mechanisms ultimately improves treatment," says Nancy Andreasen, M.D., Ph.D., professor of psychiatry, University of Iowa College of Medicine in Iowa City.

Affective Disorders: Adrenaline is released from the adrenal glands when one experiences the "fight or flight" response. In the central nervous system, an excess of a related chemical, norepinephrine, is believed to be responsible for *manic* mood swings, marked by episodes of elevated, expansive, irritable moods. In contrast, a deficiency of the neurotransmitter in certain brain regions may be related to the development of *endogenous depression*—melancholia produced by no apparent external cause. Drugs that increase available transmitter reduce depression; other drugs stabilize against manic mood swings. Many of the drugs used in the treatment of *affective disorders*—mania and depression—alter the adrenergic (adrenaline- and norepinephrine-producing) systems in the brain.

Schizophrenia: The "dopamine hypothesis" of schizophrenia postulates that excess dopamine activity in brain regions that control thought and emotion may be responsible for the development of psychotic systoms in many patients. Antipsychotic medications (also called neuroleptics), such as chlorpromazine (Thorazine, Smith, Kline & French), block dopamine receptors and often alleviate some of the most pronounced symptoms of schizophrenia. But antipsychotic drugs also block dopamine receptors in other brain regions. As a result, they frequently produce persistent and serious side effects. When dopamine receptors are blocked by antipsychotic drugs, side effects develop that may be related to up regulation of dopamine receptors.

"The dopamine hypothesis is overly simplistic," says Arnold Friedhoff, M.D., professor of psychiatry at the New York University School of Medicine in New York City. "The theory doesn't adequately account for the complex interactions that occur between cause and effect." In other words, no single theory can explain all cases of schizophrenia, and experts believe depression is similarly complex.

Alzheimer's disease: Studies suggest that nerve cell death occurs in certain acetylcholine-containing regions of the brains in affected individuals, resulting in an acetylcholine deficiency. This degenerative process may be responsible for some of the behavioral changes seen in Alzheimer's disease patients. However, unlike the affective disorders and schizophrenia, Alzheimer's disease has not responded to treatment with drugs that alter neurotransmitter levels or receptor function.

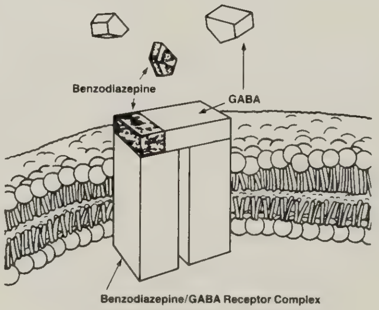
Serotonin, another abundant brain neurotransmitter, is an important regulator of appetite and mood. The highest serotonin concentration found in the pineal gland—a pea-sized structure attached to the brain that help regulate circadian (daily) hormonal rhythm. In most brain regions, serotonin has been shown to depress electrical activity. The amino acid precursor to serotonin, tryptophan, has sedative properties as well. Research indicates that drugs that prolong the effects of serotonin may be used to help people quit smoking or withdraw from alcohol. Dietary supplementation with tryptophan may reduce the amount of time required for an individual to fall asleep.

Brain Peptides: Transmitters or Modulators?

In the early 1970s, when researchers discovered opiate receptors in brain tissue, they wondered why receptors would be present for molecules that weren't believed to exist there. Later, they realized that the brain does, in fact, produce opiate peptides called *endorphins, enkephalins* and *dynorphins*—molecules formed from strings of amino acids. These peptides are found in abundance in regions associated with movement, pain perception and emotion. They appear to help control these processes.

"There is strong evidence to suggest that endorphins play a role in pain sensitivity and perhaps in the process of narcotic addiction as well," says Eric Simon, Ph.D., professor of pharmacology and psychiatry at the New York University School of Medicine. "In addition, there may be a subtype of schizophrenia that involves the endorphins, but the evidence is inconclusive at present."

FIGURE 2: **HOW ANTI-ANXIETY DRUGS WORK WITHIN THE BODY**



The receptor for gamma-aminobutyric acid, commonly referred to as GABA, has been associated with the neurochemical system that benzodiazepines work on and is thought to have a role in the control of generalized anxiety disorders. This is commonly referred to as the benzodiazepine/GABA receptor system and has been identified because of research on the molecular mechanism of action of the benzodiazepines

By some scientists' definitions, most brain peptides are not neurotransmitters, but appear only to fine-tune neurotransmitter chemistry, much as a dimmer switch on a light permits finer regulation of brightness.

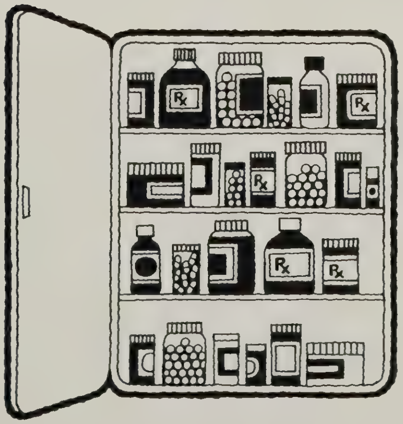
GABA—Its Role in Lessening Anxiety

For many years, scientists have speculated that the brain's capacity for function is largely untapped. It appears, however, that the bulk of the brain is busy turning off signals that would otherwise cause distraction or perhaps even seizures.

GABA (gamma-aminobutyric acid), an amino acid found in the brain, is a neurotransmitter that inhibits activity in the CNS. When GABA is released from one neuron and binds to the receptors of another, the neuron receiving sufficient GABA molecules is inhibited from firing and from releasing its own neurotransmitter. GABA is found in high concentrations in the brain, yet is curiously absent in the rest of the body.

The anti-anxiety effects of *benzodiazepine* drugs, such as alprazolam (Xanax, Upjohn), seem to be related to their enhancement of the GABA system. By promoting GABA binding to its receptor, the benzodiazepines inhibit neural activity. GABA may thus serve as the brain's central inhibitor. The bulk of the brain, which appears to serve no useful purpose may, in fact, be quietly preventing our loss of control over muscular and mental functions. Without redundant inhibitory systems, the activity of our brains might prove overwhelming, garbling information and distorting sensation by giving us too many messages at once.

Although knowledge about neurotransmitters and receptors is incomplete, certain basic principles established over the past 25 years have helped guide the development of modern biological psychiatry. Receptor technology is the foundation of much of the current search for new drugs to treat or prevent widely divergent disorders—from mental illness and pain to appetite suppression, from heart disease to the common cold.



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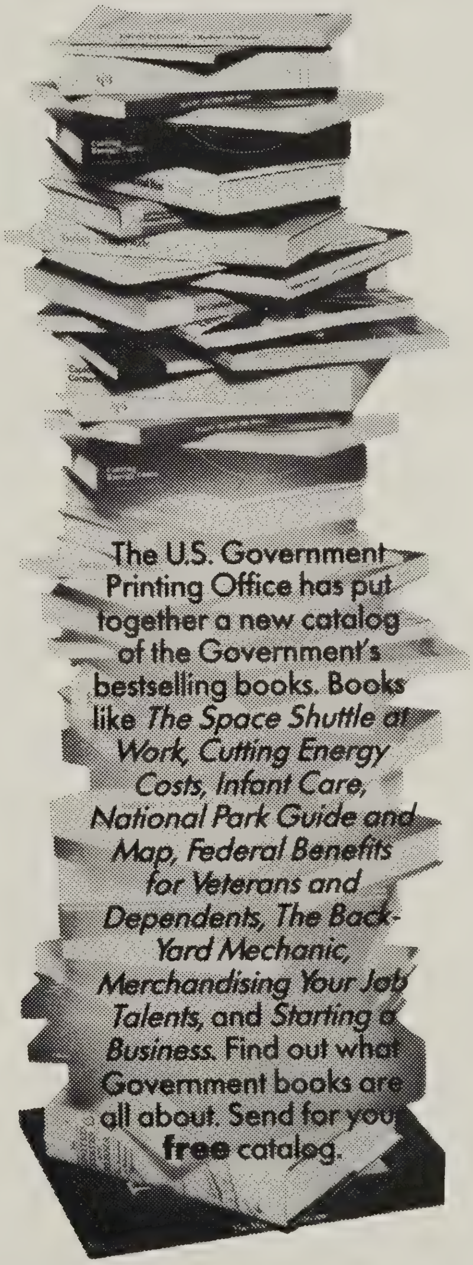

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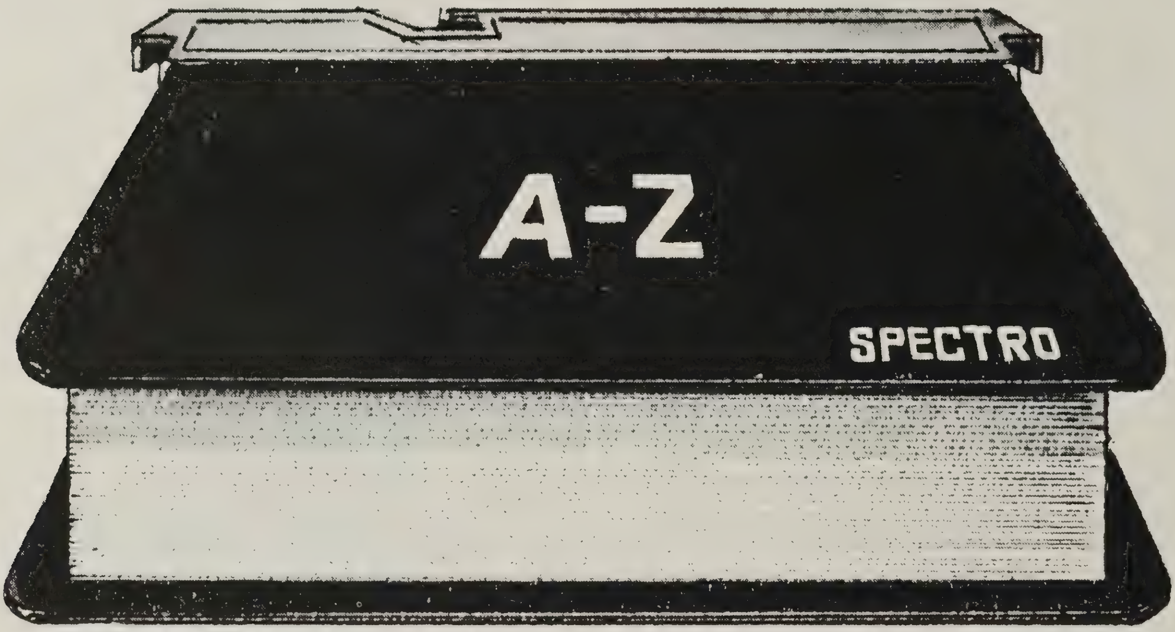

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Special Report:

Ayerst JAMA Study Rips into Pharmacy

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Generic drugs don't always save money, sometimes they're downright more expensive than brands, and use of them allows unreasonable profiteering by dishonest pharmacists.

That's the deviously brilliant but corrupt "bottom line" in a November 14 *Journal of the AMA* study for prescribers funded by the wickedest disparager in the industry, Ayerst Laboratories, which is already being sued for $40 million over its fatuous suggestions to pharmacists that substitution of FDA-rated equivalents could raise their liability insurance premiums and attract bad publicity.

The implications for PSAOs are great, because PSAO success depends largely on pharmacy integrity in cost-effective DURs.

Ayerst has an apparently endless budget for these kinds of attacks, having also recently sent selected physicians on tours during which they held local news conferences to inform the lay grassroots of the dangers of generics.

Ayerst's JAMA study, by University of Pennsylvania economists, targeted pharmacists as generic profiteers, pointing out that retail price differences between competing pharmacies were wider on generics than on brands.

"The size of differences between generic and brand drugs in cost per pill to the pharmacy was not matched by comparable differences in prices paid by consumers," the *JAMA* survey told prescribers and other drug policymakers.

"Generally, there was a larger differential in pharmacy cost than consumer price. For example, consumers paid the same median price, 12.7 cents per pill, for generic conjugated estrogen or Premarin, 0.625 mg, whereas the pharmacy paid a median of 4.9 and 8.6 cents, respectively . . . This difference in differentials is reflected in the mean gross profit (or markup) realized by the pharmacy. In 11 of 21 cases, the dollar profit of the generic drug was higher than that of the comparable brand drug. In 3 cases profit for the brand was higher than that for the generic, while in the remaining seven instances, profit per prescription was similar for generic and brand drugs. Overall, pharmacies appeared to mark up generic drugs more than brand drugs, both in percent and dollars."

Moreover, this skullduggery was no different for chains than for independents, although chain prices were of course cheaper than independent.

The study naturally omitted any discussion of such obvious considerations as the fact that brand-heavy prescribing (at least 80% of all Rxs) makes duplicative generic inventories more expensive for pharmacies.

It also failed to acknowledge that a $3 fee on a $4 generic looks worse both as a percentage and as a per-pill money figure than a $3 fee on an $8 equivalent innovator product. Ayerst's study blithely concluded that because of all the difficulties it had uncovered, and because of the obvious fact that Rx price shopping is expensive, an "always buy generic" rule is shortsighted; better to say, "always seek and buy the least expensive, whether generic or brand," even though such a rule would demonstrably be too confusing and costly in itself to be worthwhile.

What's the prescriber likely to make of the study? First, probably, that pharmacists are dishonest, and second, that as a consequence, allowing generic substitution on the Rx is of dubious value.

Ayerst, you've done it again!

* * *

Citing a series of ongoing paid physician tours to "falsely compare brandname and generic drugs" (legal talk for what lesser mortals ignorantly call disparagement, which apparently is legally fine and dandy by that name!), an NAPM-Zenith reply brief in New York federal court 11/20 says: "Plaintiffs believe that these incidents, which have been exposed even before any discovery, are but the tip of the iceberg.

"There is unfortunately no indication that the expiration of the two-year exclusivity period has put an end to these activities. "There are extremely important stakes in this latest phase of the contest which brand name companies have waged for decades. Through clever, not-so-clever, and perhaps too-clever promotional activities, the Ayersts of the world have tried to attack the quality of generic drugs as inferior to brand-name counterparts. These attacks are false and misleading."

Which is far worse than the allowable, innocent "disparaging" that FDAers, pharmacists and other uninformed people thought they were seeing in Ayerst's unscrupulous Inderal-defense promotions that prompted the $40 million suit by Bass & Ullman. Ayerst's motion to dismiss, to which the NAPM-Zenith brief replies, actually would gladly admit to its conduct being mere disparagement; it would then be "not actionable under 43(a) of the Lanham Act."

Ayerst's repugnant behavior has a long, institutional tradition at American Home Products, the NAPM-Zenith brief reminds the court. "One of the astonishing features of Ayerst's motion," it says, "is that it purports to set forth this Circuit's standards of law under Section 43(a) without mentioning the cases to which American Home Products was a party. In fact, the law of comparative advertising has advanced principally as a result of a series of cases in which AHP has been found liable for progressively more clever, but not less false, claims of superiority. It is no surprise that false comparative advertising as a way of life at defendant found further expression when its largest selling prescription drug first had to face competition."

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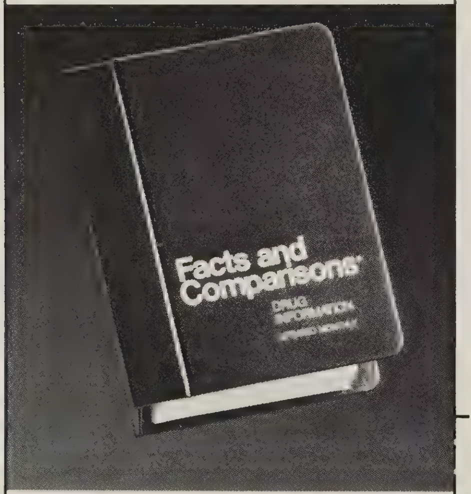

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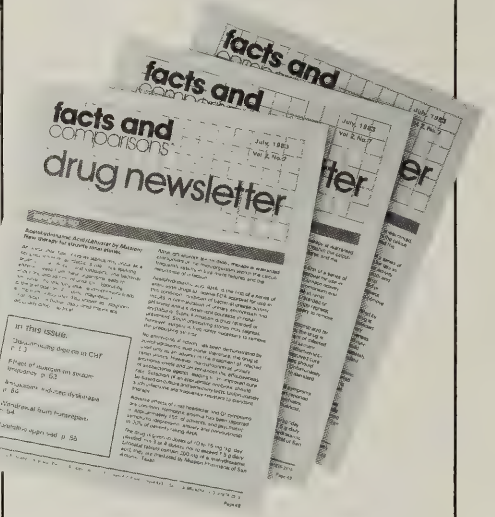

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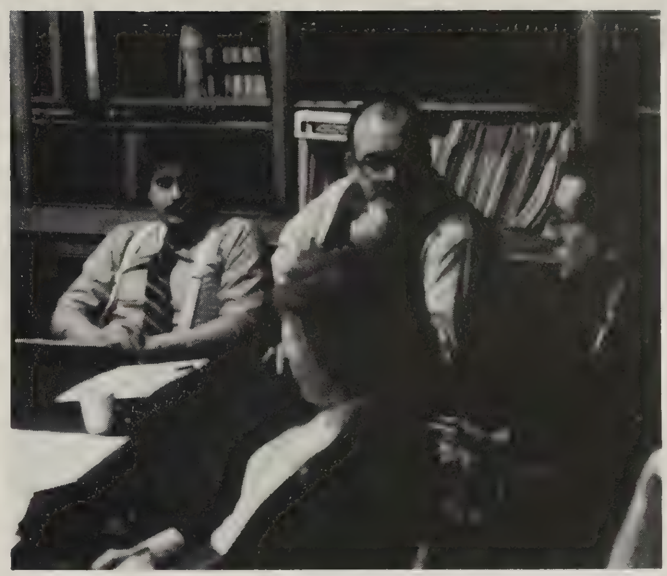
George C. Voxakis, President of the Maryland Pharmacists Association, was interviewed by WJZ-TV television reporter, Ann Kellan, on the subject of dispensing physicians. MPhA's work on this issue has generated nationwide publicity.



The annual meeting between members of the Maryland Association of Chain Drug Stores and the Board of Trustees of the Maryland Pharmacists Association was held to discuss areas of mutual concern and cooperation.

This is the best way to get Continuing Education credits. MPhA members attended C.E. lectures in the sun in Hawaii as a new part of the annual group travel trip offered by MPhA. A total of seven credit hours were offered to attendees and the program was co-sponsored by the Maryland Pharmacy Continuing Education Coordinating Council.

Stephen J. Provenza has been elected as President of the Baltimore Veteran Druggists. He is also the state representative to the American Institute of History of Pharmacy and Curator for the MPhA's B. Olive Cole Pharmacy Museum in the Kelly Memorial Building.

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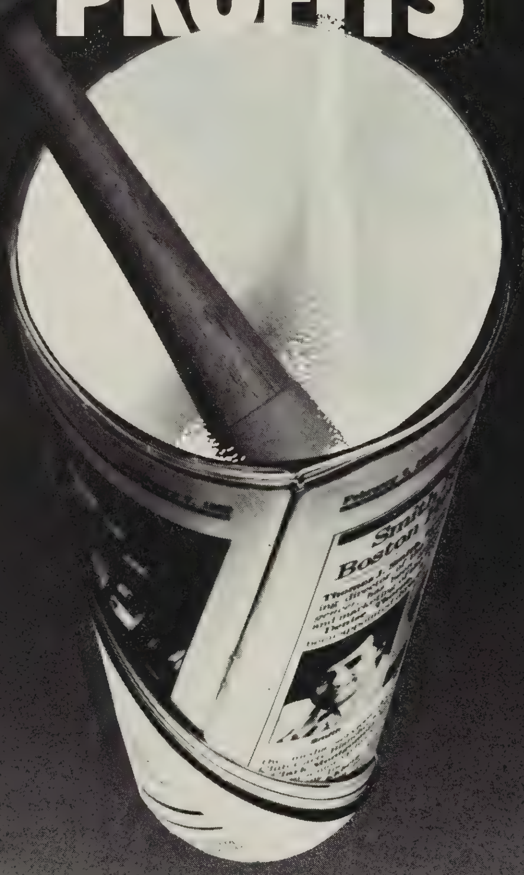

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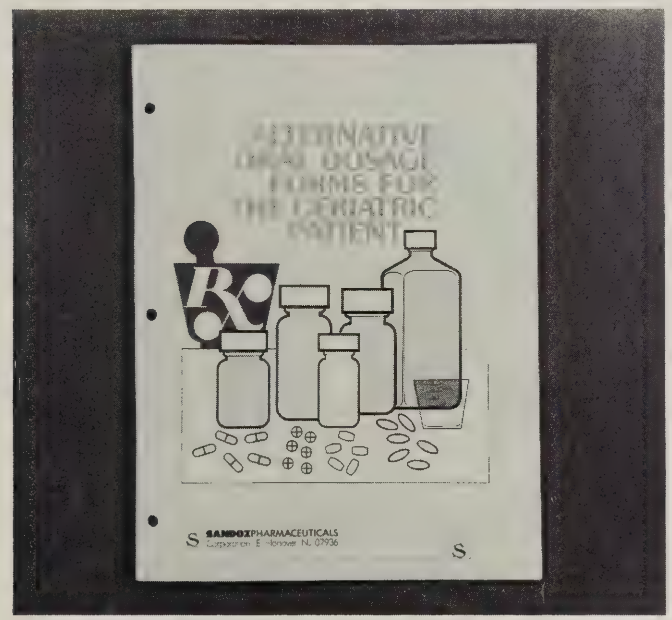
The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.



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An information guide entitled *Alternative Oral Dosage Forms for the Geriatric Patient* has been developed through Sandoz Pharmaceuticals Corporation to assist health care practitioners in administering medication to their patients who have difficulty swallowing. The booklet discusses why certain tablets and capsules should not be crushed or opened and provides information to guide practitioners in deciding whether or not to alter a dosage form. Also included in the booklet is a listing of medications currently available in liquid form. This free literature is available through a Sandoz or Dorsey Pharmaceuticals sales representative.

calendar

March 8 (Sun)—BMPA Annual Dinner Dance
March 15 (Sun)—CECC Seminar "Airway Disease"
March 15–21—National Poison Prevention Week
March 23–24—NARD Legislative Conference, Washington, D.C.
March 28–April 1—APhA AnnualMeeting
April 12 (Sun)—Berman Seminar—CECC on Cardiovascular Therapy
April 29–May 2—NARD Rx Expo in New Orleans
April 30 (Thurs)—Seminar: Chronic Care & the Elderly: An Update, Hilton Reisterstown Rd.
May 17 (Sun)—CECC Seminar on Arthritis
June 21–25—MPhA ANNUAL CONVENTION—SHERATON OCEAN CITY

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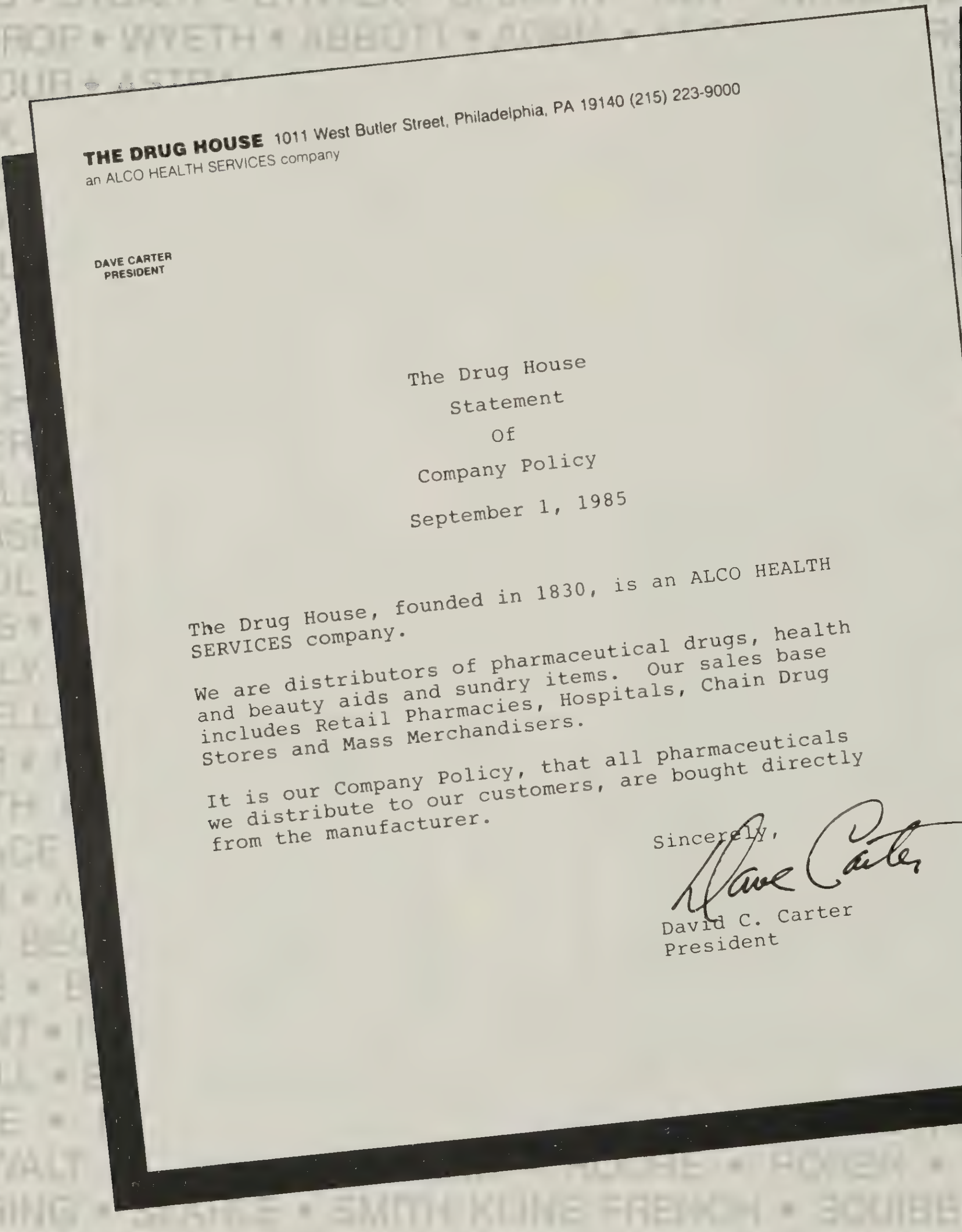

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The Future is Not What it Used To Be — *Peter P. Lamy*

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— Thomas A. Gossel
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Pharmacy Power—a Commentary — *Jim Dickinson*

The Decision on the All-Pharm.D. Program

— William J. Kinnard, Jr., Dean

Cocaine and Crack — *Joseph Scarlata*

The Compounders Corner

— Loyd V. Allen
— M. Lou Stiles

THE MARYLAND PHARMACIST

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BALTIMORE MARYLAND 21201
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APRIL, 1987 VOL. 63 NO. 4

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THE THRILL OF VICTORY . . . . .

Over the past months, I have been stressing the importance of working together for the common good. You may have tired of my constant urging—but I'm here to say that working together can work; in fact, it did!

In January of this year, the State of Maryland Medicaid Program informed the pharmacy community of its intention to implement a new policy of prescription reimbursement. The State was offering a 50-cent per prescription increase, but at the same time disallowing pharmacists earned discounts based on the total number of prescriptions filled annually. Specifically, if a pharmacy filled 14,000 prescriptions a year (all prescriptions, not just Medicaid), 1% of the cost of ingredients would be discounted by the State. The system worked on a sliding scale—the more prescriptions filled anually, the larger discount kept by the State, up to 12% off the A.W.P.

We considered this to be unfair—in fact, totally unacceptable. The MPhA, Maryland Chain drug stores and the NARD (National Association of Retail Druggists) conferred immediately. Through their combined efforts, the State reconsidered and, instead, offered a 25-cent per prescription increase, leaving the A.W.P. intact. The NARD Newsletter estimates that implementing this system would cost every independent retail pharmacist in the country $7,000 over a two-year-period—whether a member of any organization or not!

George C. Voxakis, P.D.
PRESIDENT

P.S. Just a note of thanks, with a touch of envy and a great deal of admiration, to the Eastern Shore Pharmaceutical Association for the warm and gracious hospitality extended to me at their recent Annual Meeting in Federalsburg. It was very much appreciated.

CONTINUING EDUCATION FOR PHARMACISTS

VOL. IV, NO. 3

Advising Consumers on OTC Denture Care Products

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio
and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. identify various types of OTC denture care products;
2. discuss the proper use of OTC denture care products; and
3. describe damage that can occur from misusing certain OTC denture care products.

Objectives

At the conclusion of this lesson, participants will be able to:

1. list various OTC products that are available for denture care;
2. explain how denture care products should be correctly used;
3. cite specific restrictions for OTC denture care products;
4. state the reasons why specific warning statements are required on denture care products; and
5. identify harmful effects that can result from using denture repair kits and denture relining products.

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This continuing education for Pharmacy article is provided through a grant from

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Consumers are barraged with advertising about items they can purchase over-the-counter to care for their dentures. Many OTC denture care products are safe to use as long as the directions are correctly followed. Others may cause irreparable damage to denture material, and adverse reactions to the user.

More than 50 million Americans wear dentures. They spent over $305,000,000 on denture care products in 1984. This represented a 7 percent increase in sales over the previous year. However, the value represented less than 1 percent increased sales to pharmacies, the difference attributed to grocery and department stores.

This article describes OTC products used to care for dentures. It discusses their uses and misuses, and provides important advice to edentulous (without teeth) consumers contemplating their purchase.

There are five groups of OTC products promoted for use with dentures or tissues in contact with them: cleansers, adhesives, reliners, repair kits, and topical anesthetics. Cleansers are useful; topical anesthetics are safe and effective for their intended use. But many experts advise against the use of the other three categories of products except on a restricted basis until the denture wearer obtains professional advice.

The information reported in this article reflects the opinions of these experts, which include representatives of the American Dental Association (ADA), and the FDA/OTC advisory panels on oral products.

Cleansers

Denture material collects debris, stains, and plaque just like normal teeth. These can lead to an unsightly appearance and strong odor. Plaque hardens into tartar which irritates the gingiva (gums) and is the beginning of periodontal disease.

Denture cleansers (Table 1) have chemical or abrasive actions. *Chemical* ingredients include detergents, dilute acids, alkaline peroxides and hypochlorites, and chelating agents.

Abrasive pastes or powders are essentially similar to regular toothpaste and powder dentifrice products available for cleaning permanent teeth. In general, powders are more abrasive than pastes.

Denture soaking solutions do not take the place of brushing. They supplement brushing, and serve as a medium to soak the dentures in when they are not being worn. Some cleansing solutions may actually damage dentures. For example, dilute acids may corrode cobalt-chromium denture material. Alkaline hypochlorite cleansers may cause similar corrosive action, and reportedly bleach some others.

TABLE 1

OTC Denture Cleansers

Product	Manufacturer
Complete	Vicks
Denalan	Whitehall
Denclenz	Creighton
D.O.C.	H. J. Bosworth
Efferdent	Warner-Lambert
Extar	Extar
K.I.K.	K.I.K. Co
Kleenite	Vicks
Mersene	Colgate-Palmolive
Polident	Block

Dentures should be removed and soaked in a cleansing solution overnight, and regularly brushed with a mildly abrasive dentifrice. Overnight removal relieves pressure on the gums and allows them to rest and breathe. Without this release, oral tissues can become macerated and eventually degenerate. This, and accumulated plaque, can lead to denture-induced stomatitis (inflammation of the oral mucosa).

Keeping the dentures in a liquid when removed from the mouth reduces their chance of becoming brittle. Also, it prevents shrinkage which can occur with drying.

Denture wearers should not soak dentures in chemical solutions that are not specifically intended for this purpose. Household bleach, vinegar and other acids may aid in removing certain stains and plaque. They may also damage denture material. Most effervescent tablets are to be added to warm, not hot, water to dissolve. Hot water may cause warping of some denture material.

When dentures are brushed, they should first be rinsed under running water to remove loose debris. A cleansing agent is then applied to a moistened brush, and all parts of the denture thoroughly scrubbed. They should then be adequately rinsed. The ADA recommends that dentures be professionally cleaned at least once a year.

A denture brush should be used to clean dentures rather than a regular toothbrush. These brushes are easy to manipulate and are designed to fit the contour of dentures and reach all areas.

Consumers should be instructed how to properly hold and correctly brush their dentures. They should also be told to avoid vigorous brushing with highly abrasive pastes or powders which may ruin denture material.

All cleansing solutions should be thoroughly removed from dentures before they are replaced in the mouth. Some solutions are intensely caustic and can irritate the oral mucosa. They should also be kept out of the reach of children.

Persistent stains that are not removed by OTC cleansing solutions, or brushing with abrasive pastes, should be evaluated by a dentist. They could represent a weakened area on the denture that may rupture.

Adhesives

Denture adhesives (Table 2) are reported to be the most commonly purchased OTC denture care products. They benefit some individuals by holding dentures snugly in place, especially while eating. But with continued use and in the absence of professional supervision, serious problems may result. These will be explained later.

For years, manufacturers of OTC denture adhesives have advertised that their products permit users to bite into apples or corn-on-the-cob without fear of leaving their teeth imbedded in food when they open their jaws.

The fallacies of these claims are apparent in that continued unsupervised use of dental adhesives can cause serious problems. Furthermore, there is no evidence that a person's chewing ability is improved because his dentures are held firmly.

Denture adhesive products are available as pastes, powders, and films. Commonly used adhesives include karaya gum, gelatin, carboxymethylcellulose, methylcellulose, tragacanth, and ethylene oxide polymers.

These substances work in two ways. They swell when moistened to form a mucilaginous gel. This obliterates spaces between the denture and gums, and secures a tighter fit. Also, they increase the surface tension coefficient of the fluid film between the denture and its supporting tissues. This causes the prosthesis to be anchored more solidly.

TABLE 2

OTC Denture Adhesives

Product	Manufacturer
Brace	Norcliff Thayer
Confident	Block
Corega	Block
Cushion Grip	Plough
Dentrol	Block
Effergrip	Warner-Lambert
Fasteeth	Vicks
Fixodent	Vicks
Klutch	Putnam
Orafix	Norcliff Thayer
Orahesive	Hoyt
Polident Dentu-Grip	Block
Poli-Grip	Block
Rigident	Carter
Secure Seals	J & J
Sea-Bond	Combe
Staze	Commerce
Wernets	Block

TABLE 3

Warnings Required on Labeling of OTC Denture Care Products

Denture Adhesives
(product name) is acceptable as a temporary measure to provide increased retention of dentures. However, an ill-fitting denture may impair your health — consult your dentist for periodic examination.

Denture Reliners and Cushions
WARNING: For temporary use only. Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For use only until a dentist can be seen.

Denture Repair Kits
WARNING: For emergency repairs only. Long-term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. See your dentist without delay.

Adhesives are only recommended for temporary use, as an emergency measure to stabilize dentures until the patient can obtain a dental appointment. They can be safely used as long as the individual is under the care of a dentist.

The ADA Council on Dental Materials and Devices passed judgement on adhesive products. Acceptable products include a label warning statement as shown in Table 3.

Some users of dental adhesives report that the products are messy and disagreeable to use. Large amounts of the adhesive may work out from beneath the dentures, especially the lower ones. The adhesive is then expectorated or swallowed. Some people avoid using adhesives on lower dentures for this reason. Denture wearers should be informed that leakage may occur from using too much product.

Other individuals claim that denture adhesives become foul tasting when combined with oral secretions. Adhesive ingredients may serve as culture medium for microbial growth. This can be minimized by removing the dentures, cleaning and rinsing them, and applying fresh adhesive twice daily.

Claims are also made that pastes are somewhat more effective than powders because of their moisture-resistant properties. Clinical studies have so far failed to substantiate these claims.

One major problem with OTC denture adhesives is that the need for additional adhesion increases over time as the patient continues to use the product. This can place uneven stress on underlying bone and soft tissues of the gums and mouth, enhancing their destruction. Serious oral pathology including ulcers and tumors may also develop with chronic use of denture adhesives.

Typically a person begins using an adhesive. Later when more and more adhesion is needed, he switches to a reliner. This can be the beginning of severe problems.

Consumers wishing to use an adhesive until they can see a dentist should be instructed how to correctly use it. To use a powder, a light layer should be sprinkled over a moistened denture before placing in the mouth. For pastes, a light layer should be applied to a dry denture before placing in the mouth.

Because it is not possible to apply the same amount of adhesive each time, there is a potential for the dentures to be constantly repositioned in the mouth. Consumers should try to apply the same amount of adhesive evenly to avoid this.

Denture adhesive seals can eliminate this problem. These consist of a thin film of adhesive that is laid on the denture before placing it in the mouth. The amount of product used is always consistent.

Some individuals may be sensitive to one or more ingredients in denture adhesives. The one most often implicated is karaya. It may cause runny nose, watery eyes, eczema, atopic dermatitis and gastrointestinal distress. If these symptoms appear, another product containing different ingredients should be selected.

Denture adhesive users should not add more product until the first application has been removed. To do so may possibly cause malocclusion of the dentures.

Reliners

Denture reliners (Table 4) are used by persons who hope to improve comfort and function of their false teeth. The products are intended to serve two purposes. They help secure loose-fitting dentures, and they provide a cushion to protect sore spots on the gums.

Relining products are available in different forms. They may consist of wax-impregnated gauze pads shaped to fit the denture, or be soft plastic sheets that are applied to the denture and trimmed. Ingredients in reliner products are different from material dentists use for relining, rebasing or refitting dentures.

While they may provide temporary relief, reliners and cushions used over extended periods of time can cause serious repositioning of dentures more severe than that caused by adhesives. They may cause the appliance to warp. Gingivitis, mouth ulcers, and tumors may eventually result.

When a reliner is used, it applies excessive pressure on all oral tissues, blood and lymph vessels. Since bone is in a constant state of change, improper use of reliners may be damaging. Bone growth (deposition) is balanced by bone resorption. When uneven pressures are applied to it, or on blood vessels serving to decrease the nutritional supply, bone resorption predominates and deformity may result.

Improper use of reliners may change a person's chewing efficiency. They may also create speech defects and cause facial wrinkles and aging lines to become accentuated. Bad breath can become intense from decaying food debris, plaque and microbials trapped within the reliner, or the space between the reliner and denture. Bruxism (grinding the teeth) and clenching the jaws together when talking are other problems associated with the use of reliners.

Oral Cancer. A factor known to cause oral cancer is ill-fitting dentures. Dentures worn by users of OTC relining products are ill-fitting. After the product is applied, they fit even less correctly. Pain is one of the last symptoms of oral cancer to appear. Once pain is experienced, the cancer may be advanced.

The dental literature reports on patients who wore denture reliners, and eventually felt pain, but associated it with loose dentures. In actuality, the irritation was from oral cancer.

A study of 204 patients with oral cancer showed a direct correlation between wearing dentures and the development of cancer. Irritation caused by the dentures occurred in 86 of the persons involved.

Opponents of denture reliners claim that users are sometimes caught in a vicious cycle. They apply a reliner which may initially secure a tighter denture fit and make the appliance more comfortable. But with time, the increased and uneven pressure applied on underlying bone causes it to resorb and shrink. The denture then becomes less snug and less stable. So more reliner is applied. Consequently, more bone is resorbed over time, and the denture becomes even less secure.

Officials of the American Dental Association and the American Pharmaceutical Association disapprove of the availability of dental reliner products for over-the-counter purchase. Spokesmen from these groups agree that these products are not in the public's best interest.

Consumers using reliners continue to wear dentures which should be relined, rebased, refitted or reconstructed by a dentist. Pharmacists should counsel consumers to see their dentists for professional advice. Almost all authorities agree that these products should be used only until professional help can be obtained.

FDA requires that the warning statement shown in Table 3 be included in the labeling of denture relining products.

Repair Kits

Broken dentures may be temporarily repaired using one of the repair kits shown in Table 4. Improper repair can cause serious damage to oral tissues by creating rough spots, or

TABLE 4

OTC Dental Relining and Repair Products

Product	**Manufacturer**
Reliner	
Denturite	Brimms Inc
Ezo Denture Cushions	Colorado Chemical
Snug Denture Cushions	Mentholatum
Repair	
Plate-Weld	Norcliff Thayer

TABLE 5

OTC Products for Relief of Denture Irritation

Product	Manufacturer	Local Anesthetic
Anbesol	Whitehall	Benzocaine, phenol
Benzodent	Vicks	Benzocaine, eugenol
Butyn	Abbott	Butacaine
Chloraseptic gel	Procter & Gamble	Phenol
Kank-a	Blistex	Benzocaine
Numzident	Purepac	Benzocaine, eugenol
Orabase with Benzocaine	Hoyt Labs	Benzocaine
Orajel	Commerce	Benzocaine
Rid-A-Pain	Pfeiffer	Benzocaine

placing unnatural pressure against oral tissues and stresses on the denture itself. The individual should contact a dentist as soon as possible to have them permanently repaired.

Topical Analgesics

Occasionally consumers will report their gums or tongue are sore from dentures rubbing against them. Such minor pain can be treated with the same OTC products that are indicated for toothache.

The FDA/OTC advisory panel that reviewed these items rated 85 to 87 percent eugenol (active ingredient of clove oil) as definitely effective, and benzocaine, butacaine, cresol, eugenol (less than 85 percent), phenol and thymol as possibly effective for oral mucosal pain. Of these, benzocaine and butacaine have the best track record for proof of efficacy.

All of these agents are safe for temporary use. Irritation that persists longer than seven days, or worsens, should be evaluated by a dentist, not self-medicated. Representative OTC products that are promoted for relief of pain due to denture irritation are listed in Table 5.

Summary

OTC denture care products are safe and effective when used as directed on their labels. Dentures that do not fit properly or are broken must be refitted or repaired by a dentist.

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Commentary

Pharmacy Power

by Jim Pickinson

Pharmacy power. Sometimes, in the pharmacy you can be too close to the wood to see the trees.

Take dispensing physicians, for example. The pharmacy press will tell you it's the hottest issue around, with giant repackaging companies picking up physicians right, left and center.

That's true.

Then you'll read that the Federal Trade Commission is on *their* side, and pharmacy has its back to the wall —a matter of "grave concern," as the American Pharmaceutical Association puts it.

That's only a little bit true.

Dispensing physicians are so much of a menace— not just to pharmacy, but especially to the public as a whole—that this is a very winnable fight. And better yet, it will be an interesting fight, because of the weirdness of the forces that are lined up against pharmacy.

It's a fight that every pharmacist can pitch into, with relish. The weirdest part of this is the FTC scenario. On two occasions, it has publicly spoken out against pharmacy efforts to make physician-dispensing illegal. In one, an FTC letter to the Maryland Board of Medical Examiners rendered an opinion that physician-dispensing is no more hazardous a practice than other medical practices, and that pharmacists often do not safety-check prescriptions. In another, the somewhat flaky, far-right Republican chairman of the FTC ("extremism in the pursuit of competition is no vice" [*apologies to Barry Goldwater, 1964*]) Daniel Oliver told the National Health Lawyers' Association in January that physician-dispensing is a "traditional aspect of medical practice" offering the consumer increased convenience and more-competitive prices.

These utterings have been widely misinterpreted in pharmacy as signaling: Throw-in-the-towel-unless-you-like-bleeding-to-death-in-battles-you-can't-win.

Nothing could be further from the truth!

As National Association on Retail Druggists executive vice president Charles M. West put it on February 9, the glint of fire in his usually quiet eyes: "We can turn FTC around on this, because it's right!"

That same day, NARD and its arch-enemy, the National Association of Chain Drug Store (!) joined forces in a vigorously worded news release saying they represented "virtually every retail pharmacy in the U.S.," they'd agreed on a single legislative strategy to protect the present system of medical checks and balances, and declaring that physician-dispensing "is not in the best interest of the public health, in part, because it denies the patient the advantage of a personal consulting relationship with a pharmacist."

This is where the ordinary, individual, most-respected-professional pharmacist comes in.

Hours before NARD and NACDS issued that joint statement, they had met with the FTC staff people responsible for fighting pharmacy moves to make physician-dispensing illegal or damn-near-impossible. Most significantly, they heard FTC Bureau of Competition acting assistant director Charles Corddry (write him at 6th and Pennsylvania Avenue N.W., Washington, D.C. 20580) claim, "we know pharmacists aren't consulting —we read their journals."

However, Corddry and other FTC staffers claim also that their opinion to the Maryland Medical Examiners Board is being overplayed in pharmacy—the letter was not volunteered, but requested by the board; as such, it does not reflect deep FTC concern, or a commitment to campaign in favor of dispensing physicians.

FTC's real, internal, staff-level concern (as opposed to the high-flying rhetoric of its political game-players like Oliver) is whether state licensing boards of all kinds over-reach their real, legislated authorities. When a state board asks FTC for an opinion on something that might over-reach, FTC gives it. Period.

Deep down in their institutional memories, FTC, the U.S. Justice Department antitrust division, the American Medical Association, the pharmacy associations, and all the other organizations with a long-established stake in this issue, are pretty much agreed. Checks and balanced in health care are like checks and balances in government—fundamental to the American way of life. Freedom of choice is preserved if patients aren't cut off by a prescriber's own conflict-of-interest.

Insurance companies increasingly require second opinions before elective medical expenses are undertaken. That's at least partly because the physician's judgment, alone, isn't sufficient.

News item: "The state Attorney general's Office

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has charged five Michigan doctors with having their patients' tests done at a laboratory they partly owned. They are the first cases under a provision of the state Public Health Code that prohibits doctors, dentists and other health professional from sending their patients to facilities in which the health professionals have a financial interest." *(Detroit Free Press)*

Then there is the decidedly seedy character of the people who are pressing physicians to get into this business. Many look like used-car salesmen types, glib of tongue and sleek of dress, who hire freshly minted pharmacists, out-of-work medicos and others at better-than-average salaries to exploit the financial worries of prescribers in an overcrowded, and worsening marketplace.

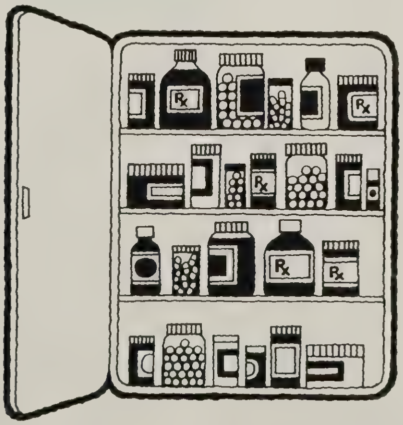
They know no more about health and checks and balances than they do about that little beauty that was only driven to church on Sunday mornings by a little old lady in Pasadena.

That's worrying the AMA, too. Their members are finding it harder to make a good living, and pharmaceuticals can offer them, according to the hucksters' brochures, $30,000 or more year income on the side. Not to be sneezed at!

Nothing worth doing is easy. Pharmacists who try to regulate state bans on physician-dispensing will attract FTC and other scrutiny. But there's nothing wrong with trumpeting the checks-and-balances system (I have 50-sheet bagstuffer pads that do it, P.O. Box 848, Morgantown, WV 26507), and giving your patients the value-added medical care that comes from one-on-one consulting.

And lend your support to the pharmacy associations that are fighting this menace for you. We don't often get a "motherhood" issue like this one!

(FOOTNOTE: You remember those letters we asked you to write to HHS Under Secretary Don Newman, R.Ph., about Medicaid discounts? It worked! Federal Medicaid has put discounts on the backburner.)



Parke-Davis, Elder-Care Program Receives APhA's Dunning Award

Parke-Davis, Division of Warner-Lambert Company, has been selected as the 1987 recipient of the H.A.B. Dunning Award presented by the American Pharmaceutical Association (APhA) Academy of Pharmacy Practice and Management (APPM).

Parke-Davis was singled out for the award to be presented at the 1987 APhA Annual Meeting in Chicago for its Elder-Care program, which was introduced in 1982 to increase communication between pharmacists and older patients. The goal of the Elder-Care program is to improve patient compliance and decrease the chances of improper medication use.

The H.A.B. Dunning Award is named for Pharmacist Henry Armitt Brown Dunning, former Chairman of the Board of Hynson, Westcott and Dunning of Baltimore, Maryland; APhA President 1929–1930; and Chairman of the APhA Headquarters Building Campaign Committee which culminated with the dedication of the American Institute of Pharmacy in 1934 in Washington, D.C. The award is presented annually by APPM to recognize an exemplary contribution to the practice of pharmacy by a pharmaceutical manufacturer.

Joseph C. Dilger, Director of Corporate Professional and Trade Relations, Parke-Davis, who for the past five years has carried the Elder-Care message to professional groups throughout the country, and who has developed several new generations of Elder-Care material, received the award at the APPM 17th annual awards ceremony on Monday afternoon, March 30, at the Chicago Hilton Hotel.

In the five years since Elder-Care was established, most pharmacists and millions of older patients have been touched by this program. The appeal of Elder-Care is the simplicity of its two part message—that pharmacists are the people older patients should consult about using their medications properly, and that pharmacists must make special efforts to reach out to senior citizens.

Working closely with Parke-Davis have been faculty members of the University of Maryland College of Pharmacy, Madeline Feinberg and Peter P. Lamy, who is editor of Elder Care News, a quarterly newsletter that goes to more than 30,000 health care professionals.

Previous Dunning Award recipients are Lederle Laboratories in 1984 for support of the "Self Medication Awareness Test"; McNeil Pharmaceutical in 1985 for its "Pharmacists Against Drug Abuse" (PADA) program; and Hoechst-Roussel Pharmaceuticals in 1986 for their team of scientist-information specialists.

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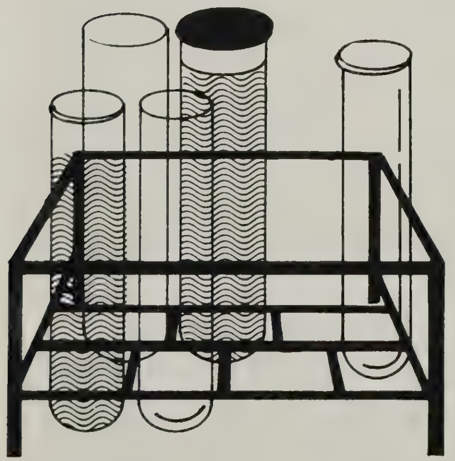
MPhA Continues A New Member Service and Journal Feature

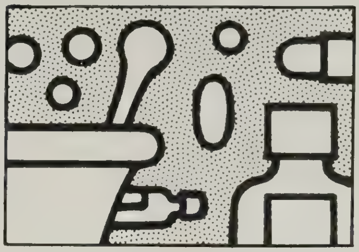
The patient education aid on the right is part of a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, MD. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other information, place such information so that it covers the artwork in the upper right hand corner.



Things You Should Know FOR YOUR GOOD HEALTH



Stroke: Prevention and Treatment

Stroke can often be prevented today. In fact, the death rate from stroke has fallen as much as 45% since 1970. This decline in deaths has come about, in part, because of new diagnostic tests and treatments. In addition, many Americans are adopting sensible health habits which lower the risk for stroke. Yet stroke remains the leading cause of death among the elderly and is responsible for a large number of nursing home admissions.

What is a stroke?

Stroke is a sudden disruption in the flow of blood to an area of the brain. Deprived of blood, the affected brain cells either become damaged or die. While cell damage can often be repaired and the lost function regained, the death of brain cells is permanent and results in disability.

Diagnosis and treatment

A stroke is a medical condition that requires immediate care. The doctor first evaluates the patient to determine if a stroke in progress has been completed. The entire episode can last from minutes to hours and sometimes (although rarely) days.

Treatment begins as soon as the stroke is diagnosed to ensure that no further damage to brain cells occurs. Strong drugs, called anticoagulants, may be prescribed to prevent blood clots from becoming larger; or, in the case of a hemorrhagic stroke, drugs may be prescribed to lower the blood pressure which is usually high.

What you can do to prevent stroke

Stroke was once viewed as a single devastating attack, but we now know it develops over a period of many years. The risk factors or conditions that lead to stroke include high blood pressure, atherosclerosis (a narrowing of the blood vessels due to deposits of fat), heart disease, diabetes, smoking, and being overweight.

You can prevent stroke by taking these steps:

- **Control your blood pressure**
- **Stop smoking**
- **Eat a healthy diet that includes protein sources low in cholesterol (such as chicken, turkey, fish and beans), skimmed milk, fruits and vegetables.**
- **Exercise regularly.** There is evidence that exercise strengthens the heart and improves circulation.
- **Control diabetes.** If untreated, diabetes can cause destructive changes in the blood vessels throughout the body.
- **Promptly report warning signs to your doctor.** Transcient ischemic attacks (TIAs) are the clearest warning that a stroke may occur; they produce temporary stroke-like symptoms such as numbness or weakness in an arm or leg, difficulty in speech, unexplained headaches, dizziness, momentary blindess and impaired judgment.

Where to get help

For information on treatment or rehabilitation services, call a university teaching hospital in your area or write to the American Heart Association, 7320 Greenville Avenue, Dallas, TX 75231. For answers to your questions about research on stroke and stroke prevention, write to the National Institute of Neurological and Communicative Disorders and Stroke, Office of Scientific and Health Reports, Bldg. 31, Room 8A06, Bethesda, MD 20892. And for information concerning Federal benefits and services on rehabilitation, write to the Clearinghouse on the Handicapped, Switzer Bldg. Room 3132, 330 C. Street, S.W., Washington, D.C. 20202. ASK YOUR PHARMACIST. He or she can direct you to other sources of information.

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THE DECISION ON THE ALL-PHARM.D. PROGRAM

by William J. Kinnard, Jr., Dean

The Faculty of the School of Pharmacy has completed the planning process concerning the types of professional degree(s) to be offered by the School. The program decision was made at a January faculty retreat following a planning period of over six months, during which time input was received from various individuals and groups both within and without the School. We are very appreciative of the advice and support provided by alumni, practitioners, and professional organizations during the process.

The changing and wide-ranging roles of the pharmacist caused by new technology, the expansion of molecular biology, and the evolution of the health care system, compounded by the unclear future manpower needs and the unstable pharmacy reimbursement system, caused the faculty to recognize the need to continue the educational evolution of its professional program, but to do so within the framework of the existing two degree system. Contributing to the decision was the faculty perception that the total financial, faculty, and space resources required to convert to the all-PharmD program would be very difficult to obtain. That would be especially true if the present overall professional school enrollment, and strong doctoral educational and research levels were to be maintained.

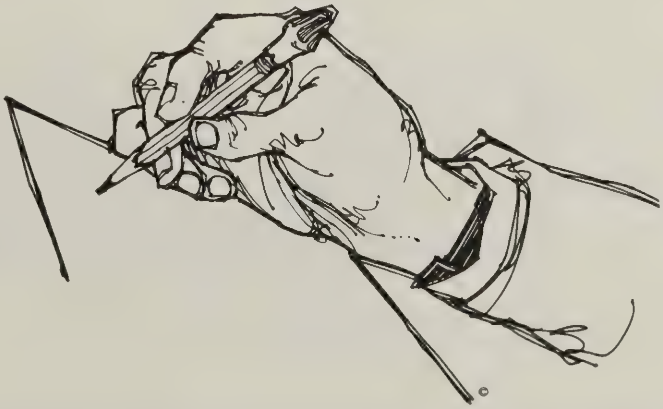
The School will continue to recognize the need to produce pharmacists with the range of skills necessary to function in the diverse roles of today's and future pharmacy practice, and in addition, will also strengthen programs designed to produce practitioners with advanced skills. It will do this in several ways; revision of the present baccalaureate program, increasing the number of PharmD students while allowing for some decrease in baccalaureate students, developing of a program to upgrade the knowledge base of existing practitioners, and establishing a post-PharmD residency program.

The curricular revision of the BS program will take into account the need to incorporate new information in knowledge areas, such as: certain basic pharmaceutical sciences, biotechnology, nutrition, immunology, adverse drug reactions, etc. In addition, the program will be structured to improve abilities in problem solving, decision making, interpersonal skills, and confidence building.

Increased emphasis on student enrollment in the PharmD program could entail a approach that would allow students to enter the PharmD curriculum as first year students, rather than at the end of the second professional year. A strong recruiting program will be needed to support the increase in PharmD program enrollment, and to maintain the quality of the baccalaureate applicants.

Programs designed to assist practitioners to upgrade their professional skills will be developed using specially designed courses as they become available from a consortium of pharmacy schools. They may be initially structured as certificate programs while the faculty further considers the structure and cost of an external PharmD program.

The proposed changes in our present programs will require additional resources, while not at the level demanded by an all-PharmD program, they will still be significant. The continued support of the School by the pharmacy profession of the State will be an essential part of our drive for excellence.



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Featured Article

The Future is not What it Used To Be

by Peter P. Lamy, PhD

PART I

The trouble with our times is that the future is not what it used to be.

Paul Valery, around 1900

There are some things vital to us that we never miss until they are gone.

It isn't how much time we take to "smell the roses", it's how we use the time we have.

Bishop Ernest A. Fitzgerald

The Health Care Revolution

Some say that the United States is in the midst of a health care revolution, others say that it is just the beginning. One thing is clear, though: evolutionary changes have given way to revolutionary ones. What has led to these changes?

The Forces of Change

Cost of Health Care: Cost of health care, the largest business in the US, has increased spectacularly and steadily (Table I), with hospital costs accounting for the largest share (Table II). Health care now consumes approximately 11% of the GNP. Fifty-three percent is covered by health insurance, but 42%, a rather considerable sum, by individuals with no reimbursement as out-of-pocket expense.

Effectiveness of Health Care: Nobody can argue that developments in the acute care sector have not led to effective health care. On the other hand, dollars spent are not necessarily related to better public health. Public health includes the control of disease as well as modifications of unhealthful behavior. It is everybody's business, and includes advocacy of healthy diets, exercise, cessation of smoking, immunizations, detection of hypertension, diabetes, and cancer. Adverse drug reactions are a problem of public health.

TABLE 1
The Rising Spiral of Health Care Cost

Year	Cost in Million ($)
1981	287.0
1982	323.6
1983	357.2
1984	390.26
1985	425.06

TABLE 2
Contributors to Health Care Costs

Contributor	Percent Contributed
Hospitals	42
Physicians, dentists	27
Nursing homes	9
Drugs	7
Other	15

Measured in that fashion, health care is not successful. The war against suicide has not been won, and against dementing illnesses has just started. The death rate from cancer has risen from 170 to 185 per 100,000 persons between 1950 and 1983, despite the $13 billion spent on cancer research since 1971. There has been no positive impact on the age-adjusted mortality rate associated with all cancers combined in the total population. As a matter of fact, in certain instances, there has been an immense increase. For example, the estimated number of deaths from malignant melanoma in persons over 65 has increased by 600% in men and 500% in women since 1950, even though if detected early and treated, skin cancers can almost always be cured. Public health measures, such as screening, though, are effective and most effective for cancers of the breast, colon and cervix. Similarly, control of cardiac and cerebrovascular disease can best be achieved by identification and modification of risk factors (smoking, hypertension, hypercholesterolemia).

Cost Shifting: The Reagan administration, in its pursuit of "federalism", has shifted many health care costs from the federal government to state governments and to employers, who, in turn, attempt to shift the cost to employees. Former HEW secretary Joseph Califano has stated that the Fortune 500 companies face $2 trillion of unfunded health liabilities.

Health Care Consumers: Unions and other employees look for cheaper health care, in an effort to prevent a lowering of benefits. Consumers (and Con-

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Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, Chairman, Department of Pharmacy Practice and Administrative Science, School of Pharmacy and Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD 21201 gress) complain that the US health care system is an inconsistent patchwork of programs designed at one time to "fix" specific problems. The public demands that there be an "unbundling" of health care costs, so that only those who receive specific services pay for them. The public feels that services to seniors and the disabled are needed most. They look for better transportation, adult day care, mental health care, wellness programs, some health care and, of course, extended hours during which health care can be obtained in the community. The public is sending a loud and clear message that it wants primarily easy access to affordable health care, with access and convenience ranking high, ahead of a personal and on-going relationship between provider and consumer.

The Demographic Imperative: The world's elderly (age 65 and over) population will soon have quadrupled, to over 1 billion people. Demographic changes in the United States mirror these developments. Between now and the year 2000, the number of 75 to 84 year olds will increase from 7.7 million to 12.2 million. There are approximately 230 million people in the United States, of which approximately 2.5 million (somewhat more than one percent) are 85 years old and over. Between 1953 and 1978, the oldest-old (85 and older) increased over 200%, to a large degree because age-specific death rates decreased. This population is expected to have doubled by the year 2000, and by the year 2050, it will constitute five percent of the total population. Within the group of the oldest-old, those 95 years and older are increasing more rapidly in number. Thus, there is an elderly population that is increasing disproportionally both in number and in proportion. Importantly, every five years there is one-third turnover among those 65 years old and over, creating an ever more heterogeneous group with different expectations, aspirations and needs.

. . . And Its Consequences: Those 85 years old and over have the highest inpatient hospital utilization rate of any age group. The leading diagnoses, procedures and their disposition after hospitalization differ from those for younger adults. They are presented in Figures 1–3. However, the growing number of the oldest-old will undoubtedly place entirely different demands on the health care system. Chronic disabilities rise with advancing age. In the general population, 15% are afflicted with chronic disabilities. That increases to 35% among those 65 to 74 years and to 66% among the oldest-old. A male, being 68 years old in 1986, has a life expectancy of approximately 13 years, of which four will be years of progressive incapacity. In contrast, a female being 68 years old can expect to live another 20 years, but roughly half of these will be years of progressive incapacity. This points out two major problems that will have to be approached in the very near future. First, the health, social, and economic problems of the aged especially the oldest-old, are mainly problems of women, because women outnumber men almost 3:1 in that age category. Secondly, women are more prone to chronic diseases than are men.

Vision, hearing and speech impairment and cognitive impairment often lead to dependency. It is most important, then, to recognize that functional disabilities will provide the greatest challenge to the future care of the elderly (Figures 4, 5). Dementia and arthritis will far outstrip hypertension and diabetes as the problems of old age. The additional impact of ischemic heart disease, hypertension, diabetes and cancer will be minimal, compared with that of dementia, arthritis, peripheral vascular disease, and cerebrovascular disease. Furthermore, chronic functional diseases are often accompanied by a large number of psychological problems. Among rheumatoid arthritis patients, for example, there is a considerable incidence of suicide, depression, sleeplessness, compulsivity, and hysteria. Multiple chronic problems can be devastating to elderly. Nineteen percent of elderly with one arthritic disease may be unable to perform activities of daily living. This figure may rise to 94% in persons with two arthritic diseases.

Leading procedures, patients 85 and over

- **Lens extraction**
- **Insertion of prosthetic lens**
- **CAT scan**
- **Reduction of fracture**
- **Insertion of pacemaker**
- **Arthoplasty of hip**
- **Prostatectomy**

FIGURE 1

Source: Division of Health Care Statistics, National Center for Health Statistics: Unpublished data from the National Hospital Discharge Survey for 1983

Leading principal diagnoses, patients 85 and over

- **Cerebrovascular disease**
- **Fractures all sites**
  - **Fracture of neck of femur**
- **Malignant neoplasms**
- **Congestive heart failure**
- **Pneumonia**

FIGURE 2

Source: Division of Health Care Statistics, National Center for Health Statistics: unpublished data from the National Hospital Discharge Survey for 1983

Right now, perhaps as many as four to five million community-living elderly are limited in their ability to perform activities of daily living or are cognitively impaired (IADL impaired) and that number may well double or even quadruple in the future.

The Long-Term Care System: The United States is spending approximately $4,400 per capita each year for the health care of those 65 years old and over. About 44% of health care costs of the elderly are covered by Medicare. Medicare does not cover many illnesses requiring hospitalization, outpatient care, dental care, long-term care, or preventive care. According to the Office of Technology Assessment (US Congress), co-payment and deductibles are too high (yet they are scheduled to rise once again) and elderly now pay more out-of-pocket (in constant dollars) for health care than before Medicare was enacted. Policies are too complicated to understand and follow, especially for those without help. Elderly citizens have enjoyed access to intense acute care for some time, and sophisticated medical services and high technology intensive care have been made possible for them by Medicare. In reality, the acute-care medical model is virtually the only national response to the elderly's health needs. While some attempts have been made to meet the long-term care needs of the elderly, the evolving system is haphazard, cumbersome, and often ineffective. Programs intended to help older persons are not well coordinated, and the failure to develop a serious effort to coordinate the management of long-term care services within the community has resulted in a limited program providing only acute and episodic care. Ageism continues in the health care field, because the health care provider never sees robust, working elderly, but only the ill, the frail, the confused, or the institutionalized. Yet, clearly, the frail elderly will need the best of high technology and modern therapies for acute care, and lower-tech medical and support services for long-term and convalescent care.

Long-term care requires understanding, compassion, and the provision of hope and cheer. It requires "care" to address human concerns and it requires the skills of multiple consultants. Indeed, there is growing acceptance of the special multidisciplinary skills and knowledge needed in the long-term care of older adults.

To meet the needs of a growing, functionally dependent population, the system will need reorganization so that it recognizes (and reimburses) the need for various personal care services, providing a linkage between medical and nonmedical services. It will also mandate a re-definition of medical services, to include the many consultative services necessary.

The Agents of Change

Those who suggest and fight for changes may well be labeled as "interest-group" liberals, fighting on behalf of the "few" (in case of the elderly almsot 50 million people 55 years of age and over) against everybody else. There are already calls for "generational justice" and, indeed, one ought not to overlook the needs of others. For example, the entire long-term care system is geared to the needs of the elderly. It is not able to

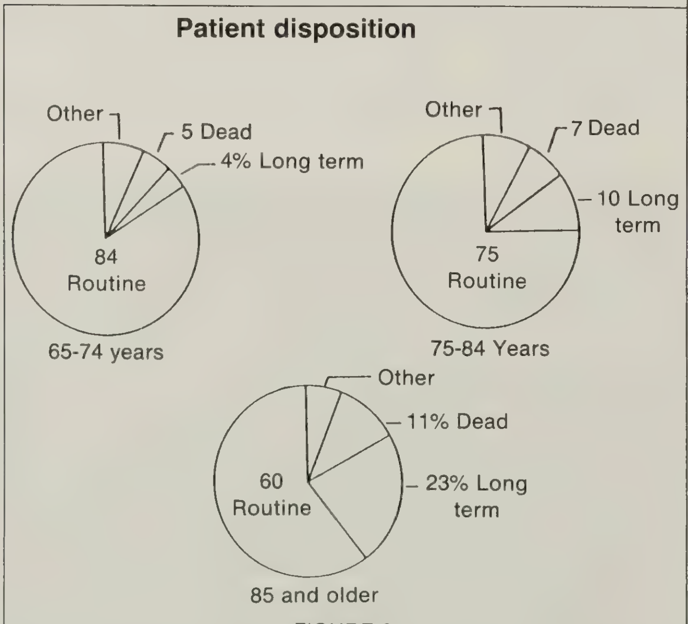


FIGURE 3

Source: Division of Health Care Statistics, National Center for Health Statistics: Unpublished data from the National Hospital Discharge

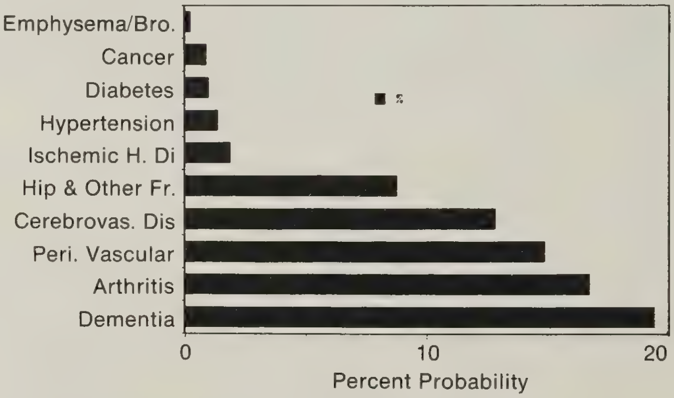


FIGURE 4

Probability of Selected Medical Conditions as the First Reported Cause of Chronic Disability Among Disabled Persons, 85 Years and Older: United States 1982

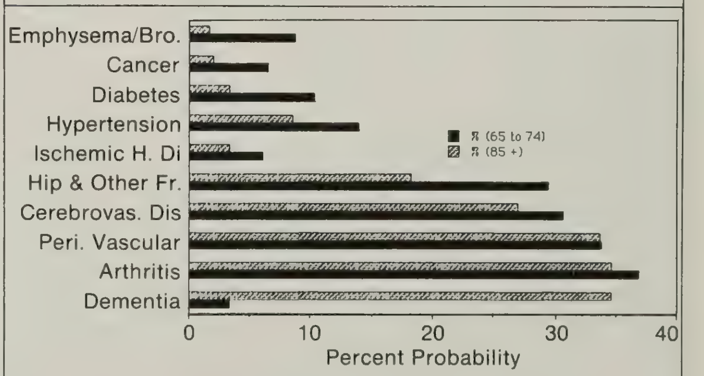


FIGURE 5

Changes over age (from 65 to 74 to 85+) in the Probability that a Chronically disabled person reports a selected medical condition as a cause serve the permanently disabled and the growing number of very young patients with cancer, or the mongoloid children, or a host of others needing long-term care.

The changes in the health care system that have occurred have served to jettison many illusions. Often, health care providers feel that they can no longer do "the right thing", even when it is obvious to them and others what the "right thing" is. On the other hand, health care providers should not fool themselves into thinking that the national interest is only an extension of their own interest. Yet, one cannot and should not tolerate and condone those who have decided that "it's no sense to confront changes, that there is no time and energy to do that". One cannot condone health care providers who distance themselves from today's issues and tomorrow's challenges, disillusioned that others do not immediately see and accept what they have to offer.

Changes in the Component Parts of the Health Care System

As a result of the continuing and unabating escalation of health care costs to business, the last several years have seen a remarkable increase in the manner of tools and mechanisms developed to limit this unrelenting escalation (Tables III & IV). Cost-containment will be the ultimate determinant of virtually all aspects of health care and health care delivery (perhaps some revenue-neutral programs will survive to some degree). Indeed, health care professionals must become familiar with the "language of change" (Table V). Change will not stop at institutions, as is evidenced by the possibility of Medicare outpatient DRGs. As part of these changes, it is a certainty that the role of the so-called physician-extenders will be re-evaluated and those professions which have not established an independent role, as opposed to a delegated role, may face issues of survival.

The Hospital: The changing face of the acute care hospital is depicted in Table VI. While the number of hospitals has not changed dramatically, the number of beds and the cost have. In part, that may be because since 1950 such services as open heart surgery, respiratory (inhalation) therapy, renal dialysis, home care programs, computer tomography scanner, cardiac catheterization, speech therapy, hospice care, and genetic counseling have been added as routine service. In 1980, hospitals also accommodated 204,042,862 outpatient visits.

While physicians remain the key to a consumer's selection of a health care facility for patients not in managed care plans, 31% of all admissions are now determined by the physician in concert with the consumer, and 37% by the consumer alone. Currently 38%

TABLE 3
Cost-Containment Activities

1. Co-payment
2. Deductibles
3. Pre-admission Review
4. Concurrent Review
5. Retrospective Review
6. Hospital Bill Audit
7. Health Promotion
8. Drug/Alcohol Program
9. Generic Drug Requirement
10. Offer PPOs
11. Offer HMOs
12. Offer Dental/Mental health PPOs
13. Coordination of Benefits

TABLE 4

Maryland FIRMS PROVIDING COST CONTAINMENT ACTIVITIES

x = In Place

o = Considering Establishing

	Co-Payment	Deductibles	Pre-Admission Review	Concurrent Review	Retrospective Review	Hospital Bill Audit	Health Promotion	Drug/Alcohol Program	Generic Drug Require.	Offer PPOs	Offer HMOs	Offer Dental/Mental Health PPO	Coordination of Benefits	Other
1. AETNA	x	x				x	x	x					x	
2. Beech St. Inc.			x	x	x	x								A
3. Blue Cross/Blue Shield	x	x	x	x	x	x		x	x	x		x	x	A
4. CMP											x			
5. Care First	x										x		x	
6. Changing Point								x					x	
7. CIGNA						x							x	
8. Columbia	x										x		x	
9. Connecticut General	x	x	x	x	x	x							x	
10. Criterion			x	x										A
11. Equitable														B
12. Equifax						x								
13. Express Pharmacy														D
14. Free State											x		x	
15. General American	x	x											x	
16. GHA											x			
17. Health America											x			
18. Health Care Compare			x	x	x									A
19. Health Related Services, Inc.			o	o			x							A.E,F
20. Hopkins HMO											x			
21. Intracorp			x	x	x									
22. Kaiser											x			
23. Lincoln National		o	o	o	o	o			o	o	o	o		
24. MD-IPA											x			
25. Major Medical		x												
26. MD Foundation of Health Care			x	x	x									
27. MD Foundation of Medical Care			x	x	x									
28. Massachusetts Mutual		x				x							x	
29. Mercy Hospital							x	x						
30. Metropolitan Life Insurance	x	x	x	x	x	x				o		x	x	A
31. PCS									x					
32. Paid Prescriptions									x					
33. Physicians Care											x			
34. Prudential	x	x	x	x	x	x							x	C,E,F
35. Sinai Fitness Center							x							
36. Travelers Dental Plan														B
37. United Health Care Inc.			x	x										
38. U.S. Administrators			x	x			x							E,F
39. Washington Co. Health Dept.								x						
40. Willse & Assoc., Inc.	x	x	x	x	x	x								

A = Second Surgical Opinion
B = Dental
C = Home Health Care
D = Mail Order Drugs
E = Case Management
F = Hospice

TABLE 5
The Language of Change

- Alternate (Care) Delivery Systems (ADS)
- Capitation vs. fee-for-service
- CMP (competitive medical plan)
- COBRA
- Cost shifting
- DRGs
- Drug utilization review
- Flexible benefits
- HMOs
- Managed care
- Market segmentation
- PPOs
- Prepaid health care
- PROs
- Prospective pay
- Shared risk design
- TEFRA
- The "other" drug problem
- Therapeutic substitution

of all inpatient days are attributed to those 65 years old and over. This will increase by 12% by 1990 and by another 20% by 2030. Other statistics indicate that hospital inpatient days will rise from 264.7 to 303.4 million between 1980 and 1990, with 90% of the increase attributed to the elderly. In 1983, there were 1.5 million discharges for patients 85 years and older in short-stay non-federal hospitals, or six discharges for every 10 persons in that age group, in contrast to 1.5 discharges/10 persons of all ages. Of all discharges, looking only at those 85 years and over, one-third were 90 years and older. Surprisingly, in view of the fact that women outnumber men substantially in that age group, discharge rates were higher for men than for women. Quite obviously, the hospital must learn to deliver services to the elderly. On the other hand, many hospital stays of non-elderly adults are inappropriate and avoidable. One study by the University of California/Rand Corporation showed 23% to be inappropriate and 17% that could have been treated in an ambulary setting.

Change continues, and the rate of change is accelerating. The number of hospital beds is decreasing, as is the average length-of-stay. In the future, fewer real government and private insurance dollars will be available for inpatient care services. Hospital administrators must decide whether they wish to capture the "lost" dollars by new services in the ambulatory setting. Apparently, the decision has been, in the main, a resounding "yes". Still another argument has been advanced. Decreased length-of-stay before and after hospitalization was a result of the need for cost containment. In the future, hospital stays will be even shorter. Thus, it has been argued, excellent follow-up will be needed to negate the possibility that early discharge would lead to complications. Therefore outreach programs need to be established, as well as programs to meet the increasing needs of the elderly population. According to a recent survey by the American Hospital Association, 66% of all community hospitals plan to develop or expand services for the elderly (Table VII). Perhaps that expansion into the community is one reason why it is anticipated that hospital education departments have been identified as one growth area. It might be added that a number of hospitals have also established hospice programs and respite care programs.

While general acute care hospitals and especially tertiary care hospitals face further, major changes, specialized hospitals may well thrive in the future.

Psychiatric Hospitals: Their number is increasing rapidly, particularly in states where a certificate-of-need is no longer required (Arizona, California, Kansas, New Mexico, Texas, and Utah). Psychiatric Institutes of America now operates 38 psychiatric hospitals, and Charter Medical Corporation operates 52. Of the 6,000 general acute care hospitals, 1,358 operated psychiatric units in 1984, up from 1,224 in 1980. It is estimated that about 10% of the elderly suffer from mental status changes, a number that will grow precipitously with the aging of the elderly population.

Rehabilitation was a $4.5 billion business in 1985, and is estimated to reach $11 billion by 1990. One reason for the expected growth, of course, is the growing aging population with chronic illnesses. Rehabilitation will be offered more frequently to add quality to the aged patent's life. Musculoskeletal injuries, neurological illnesses, and arthritic conditions probably occupy the area of most intense need. In 1986, there were 73 rehabilitation hospitals with 11,400 beds (exempted from Medicare's PPS system) and there were 6,600 rehabilitation beds in acute care hospitals. It has been estimated that there will be 160 rehab hospitals in 1990 with 14,400 beds, and that the number of beds in other hospitals will increase to 28,000. Additionally, there are 97 comprehensive outpatient rehabilitation facilities (CORFs), a number estimated to rise to 200 by 1900.

Corporation and Managed Care Systems: One of the major approaches to cost-containment has been vertical integration of several different health care systems components, or the formation of multi-facility systems. The argument has been advanced that in super-large organizations the hospital may well become just one of many subsidiary corporations (the parking garage or the catering service may be others) managed by a principal corporation and thus would no longer be the primary or even a major concern of its corporate owner. Business concerns may well dilute the necessary single-minded approach to patient care.

Consumer awareness of hospital chains or integrated chains is still low. National awareness is about 30% and negative comments are especially found among older consumers.

TABLE 6
General Short-Term Nonfederal Hospitals

	1950	1980
Number of hospitals	5,031	5,764
Number of beds	504,504	978,830
Average daily census	371,837	739,277
Average length of stay (days)	8.1	7.5
Expenses per patient day	$15.62	$280.53
Payroll expenses per patient day	8.86	136.51
Full-time personnel per occupied bed	1.8	3.8

TABLE 7
The Changing Role of the Acute Care Hospital

	Percent Offering or Projected			
	Home Health	LTC Service	Adult Day Care	Nurs. Home
West	54	71	23	43
Upper Midwest	57	72	30	41
Southwest	47	57	23	26
Midwest	61	73	30	38
Southeast	28	44	26	33
Northeast	44	64	30	40

Chains now own 25% of North Carolina's 164 nonfederal hospitals, a 320% increase from 1980. American Medical Services, Inc operates 21 nursing homes with 3,941 beds in three states. It also owns and operates three retirement centers. AMS generated revenues of $65.9 million and pre-tax earnings of $6.6 million last year. It has agreed to be acquired by Transworld Corp of New York. Major subsidiaries of Transworld are the Hilton International hotels, the Canteen Corp, and the Interstate United Corp.

Beverly Enterprises (Pasadena, California) is an investor-owned company which operates more than 1,200 nursing homes with 125,000 long-term care beds. To meet the competition of the Irving, Texas-based Voluntary Hospitals of America, 16 Northern California hospitals have formed an alliance. HealthOne and Health Central, two major not-for-profit health care providers in Minneapolis—St. Paul will probably join forces, creating the largest provider of obstetrical, medical-surgical, and emergency care, with 21% of total hospital admissions in that area. It would be the leading provider of home health care, behavioral- and medical services, and medical transportation. The new organization, with assets of over one-half billion and revenues of $436 million, would represent approximately 1,500 physicians, 8,000 employees, and 12 managed hospitals. These examples have been cited to illustrate why there have been predictions that in 10 years the 300,000 firms now providing medical care in the United States will be reduced to perhaps 10 medical mega-corporations.

Nursing Homes: As acute care hospital beds continue to decrease, the need for nursing home beds continues to grow. Almost three-quarters of all nursing home residents are 75 years old and over, and more than one-third are 85 years old and over. Seventy-one percent of all nursing home residents are female.

According to a recent survey, there are 17,819 nursing homes with 1,508,732 beds and 1,378,702 residents. There are an additional 8,030 residential facilities with an estimated 133,335 beds and 114,704 residents. Only 18% of all nursing homes have less than 25 beds, but 89% of residential homes have less than that number. In addition, there are approximately 100 hospital-based nursing home facilities in the Veterans Administration system with approximately 9,000 beds. Some projections (Table VIII) show that the number of nursing home beds will have to be more than doubled, but economists doubt that this will happen. Furthermore, it is anticipated that the current nursing home distinction (SNF and ICF) will be blurred, creating one large system, more amenable to management and reimbursement. Others have projected an increased need for specialization, either by facility or by sections within a facility. Already, nursing home service has changed dramatically. The number of nursing homes offering chemotherapy, IV service and TPNs is rapidly growing. Nursing homes are integrating with hospitals and home care agencies. Thus, anticipating specialization is not too unrealistic. Respiratory therapy, cancer care, and dialysis may well be functions offered by nursing homes as part of their long-term care services. This, of course, would demand a broader educational base for health care providers who currently are mainly geared to provide services to elderly, particularly elderly with chronic care problems.

Health Maintenance Organizations: There are approximately 480 such organizations, of which about one-half are for-profit organizations. Enrollees are promised regular check-ups, usually no deductibles, reimbursement for 100% of care given, little paperwork, full maternity benefits, and, in general, 20% more benefits than conventional plans offer. The biggest for-profit HMO is Maxicare in Los Angeles, which has 690,000 members and projected revenues of $1.6 billion. Health Care USA, located in Blue Bell, Pennsylvania, has 768,000 members. HMO members use only one-half the hospital care compared to the general population (400 days/1000 members vs. 950 days/100 general population).

Concerns have been raised regarding the "gatekeeper" concept or the primary care case management system used by HMO's. Under this concept, the patient is assigned to or may select, from a predetermined group, a primary care provider physician, who will provide all basic or general health care and must approve the provision of all other services, including referral to a specialist or hospitalization. The concern is that treatment may be untimely and inadequate. The American College of Surgeons has noted that "using cost as an overriding determinant . . . of medical care may result in (care that is) neither timely nor provided by a fully qualified practitioner. Definitive care at the outset may avoid the false economy of beginning with inadequate, lesser procedures that ultimately give way to the treatment or operation that should have been done initially."

As of April 1986, 16 states have been granted freedom-of-choice waivers by HCFA to establish primary case management programs for Medicaid recip-

TABLE 8
Nursing Home Projections

Year	Population/Millions
1980	1.22
1990	1.69
2000	2.19
2010	2.60
2020	2.99

TABLE 9
Illnesses/Problems Most Commonly Treated
(order of frequency)

Heart/circulatory problems
Hypertension
Diabetes
Carcinoma
Post CVA
Respiratory ailments
Bowel/bladder problems
Skin problems, pressure sores
Nutritional problems

ients. Major features may include, using Arizona's Health Care Cost Containment System (AHCCS) as example: (1) a statewide competitive bidding process by health care providers for a service contract; (2) restriction on patient's freedom-of-choice in selecting providers; (3) primary care physicians as "gatekeepers"; (4) prepaid capitated funding for participating health plans as an alternative to fee-for-service payments and (5) capitated payment by HCFA to the state of Arizona. This concept is gaining support. Thirteen university hospitals, community clinics and HMOs in 10 different states are currently receiving grant and other support to develop prepaid managed health care programs. Physicians and institutions are paid a set amount per year for each enrollee and, in turn, are responsible for all of the patient's needed medical care.

Home Care: For every resident in a nursing home, there are almost four persons living in the community of equally poor medical status. Economic restrictions and desire by family and patient have led to a rapidly growing home care sector, which is, indeed, the fastest-growing segment of the health care system. The American College of Physicians, in a recent policy statement, estimated that home health care sales will have increased from $6 billion in 1983 to $25 billion in 1995. Incidentally, the same statement also reported that "physicians are too frequently not involved in home care." In 1966, there were 993 Medicare-approved home health agencies, a number that had increased to 5,071 in 1984. Essential facts about the home care sector are given in Tables IX to XII. Nineteen Living-at-Home programs have been set up nation-wide to help elderly people to remain at home through providing financial, health, and emotional assistance.

Four groups of home care patients have been identified, all of whom must be addressed individually. All have one thing in common: they need help. Help is most often given by an informal care structure, the caregiver. It is expected as "only natural" that a family give care to older relatives. Indeed, they do. Eighty percent of elderly have living children. Of this number, 75% live in the same household or within 30 miles of their adult children. Thirty percent of single elderly males live with their children, whereas 50% of single women live with their children. About 30% of unattached older American parents over the age of 75 live as dependents with their children, who serve as caregivers. The family is still the primary basis for the security of older adults in later life. Over three million family units provide major physical, personal, or financial help to their disabled community-living elderly family members. Informal caregivers provide three times as much care as do all nursing homes, hospitals, and other institutions combined. Key support is most often given by the daughter or daughter-in-law, often called the "woman-in-the-middle".

Caregivers are concerned with health promotion and eliminating, to the extent possible, psychosocial factors threatening the home care patient. However, the total burden of long-term care is certain to increase.

Caregivers are often depressed, unable to cope, and exhausted, needing respite care which is not provided. Home health care eligibility criteria are still too vague, and fiscal intermediaries deny approximately 3.5% of home health care claims. Vague eligibility rules may force more patients to enter nursing homes, as may the caregiver's lack of well-being.

TABLE 10
Number of Home Visits by Discipline

Agency total	13,530
RNs	7,025
LPNs	624
Physicians	14
Physicians therapists	1,838
Speech therapists	374
Occupational therapists	319
Medical social workers	253
Homemaker-home health aide	5,722

TABLE 11
Referral Sources for Home Health Agencies

Source	Percent of Total
Hospitals	48.2
Private physicians	25.7
Family or friend	8.5
Community service agency	5.5
Government agency	5.3
Long-term care facility	4.0
Self-referral	2.8

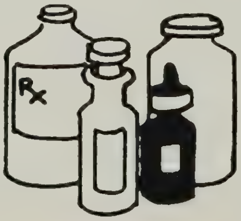
TABLE 12
Causes for Termination of Home Care Services

Reason	Percent of Total*
Self-sufficient	46.3
Admitted to hospital	18.9
Patient died	15.7
Client no longer eligible	10.9
Coverage no longer available	9.4
Admitted to long-term care	7.7
Patient refused service	3.9
Patient referred to other agency	3.6
Other	8.5

* Percent exceeds 100 since more than one reason may be given

* * *

Editors Note: Part II will appear in the May, 1987 issue on "Charges Directly Affecting Traditional Pharmacy."



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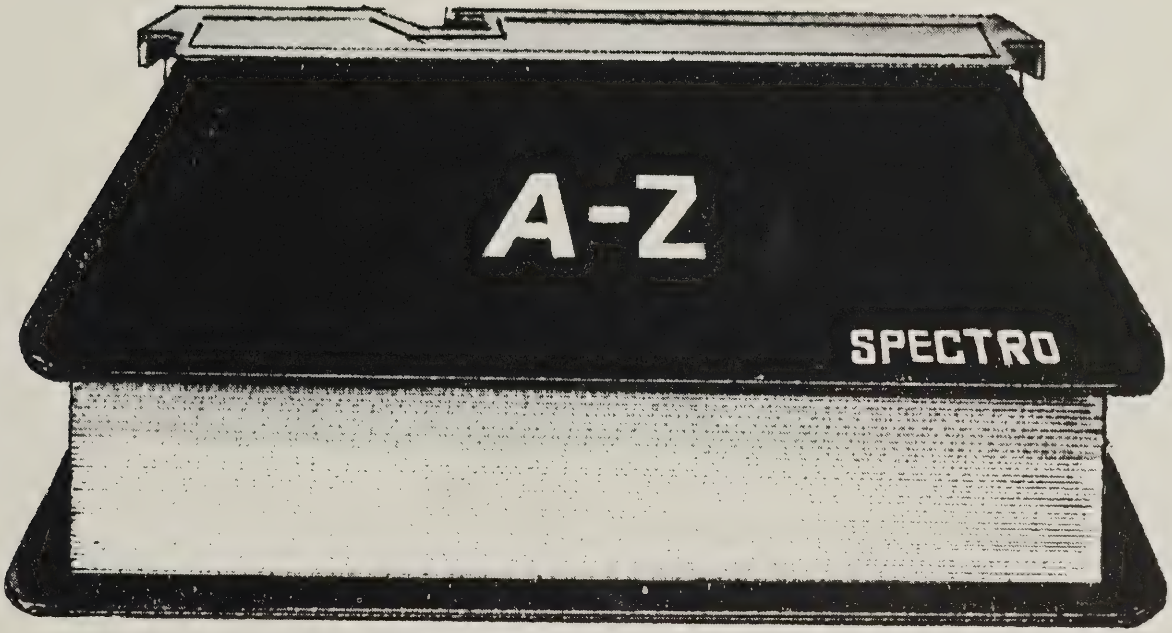

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Cocaine and Crack

by Joseph Scarlata

Like millions of others during the past few months, I have become increasingly aware of—and concerned about—the rapidly spreading use within our nation's "drug abuse subculture" of cocaine and its deadly derivative, crack.

The more I have learned about crack, the more I have found myself pondering what we, as pharmacists, should—or can—do about the situation.

Crack, as everyone knows by now, is the "free base" derivative of cocaine. But, unlike cocaine, crack is smoked rather than snorted.

The problems associated with addiction to heroin and other hard drugs seem to pale in comparison with the problems of those who fall prey to the enticements of crack.

With crack, addiction can be instantaneous. Most users are hooked after their first try. Crack users do not experience a "break in" period during which addiction develops gradually.

Unlike the other illicit drugs that plague our society, crack—or "rock" or "base" as it is also known—is relatively inexpensive. A single fix sells on the streets for about $10 to $15—putting it within financial reach of the very young. Crack is also plentiful and easily obtainable.

Law enforcement officials estimate that each day some 2,000 Americans try cocaine or crack for the first time. Most of them are teenagers.

Crack is more addictive than heroin—and it produces a greater high than heroin does. Addicts say that their cravings for crack far exceed their desires for food or oxygen.

As the most addictive drug now known to man, crack has the capacity to transform the occasional cocaine user into a desperate, fanatical addict.

ATOM BOMB

One narcotic officer has declared that crack is to cocaine what an atomic bomb is to an ordinary bomb.

Cocaine and crack constitute the fastest-growing drug abuse problem in our nation today. And it is a problem among young adults and schoolchildren.

To those of us who have been educated in the actions and effects of drugs, it is particularly horrifying to see cocaine use glorified as trendy and fashionable among show business personalities and the rich. It is appalling to see athletes, who should be role models, use cocaine with what seems to be almost unimpeded regularity.

As pharmacists, we are well aware of the hazards cocaine poses to mind and body. It accelerates heart rate, increased blood pressure, interferes with performance and produces sudden—and fatal—seizures.

This is a time for us to consider what we pharmacists, as society's most visible and readily accessible authorities on drugs, can do about the burgeoning epidemic of cocaine use.

For years, we have heard that we have a responsibility to become active in our communities, to speak out against the ravages of drug abuse and to try to educate young people about the hazards of illicit drugs.

But even though a number of our professional colleagues have taken part in such efforts, most of us have not. The pressures of business and family, we have no doubt rationalized, leave us no time to participate in programs of drug abuse education. "Someday," we have all promised ourselves, we *will* have the time. And *then* we'll become active.

TOLL RISES

Meanwhile, as we await the arrival of that "someday" when our time will be freed up, the clock

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Joseph Scarlata, senior vice-president, Pharmaceutical Group, Sterling Drug, Inc., received his bachelor's degree in pharmacy from Brooklyn College of Pharmacy in 1954.

Cocaine and Crack
by Joseph Scarlata
Reprinted with permission from "American Druggist", November, 1986

goes on ticking. The toll of people falling victim to drugs like crack and cocaine continues to rise.

Government and law-enforcement agencies can only do so much. Reducing the supply of the drugs is only part of the solution. As long as there is a demand for the drugs, ways will be found to supply them.

It is up to us to help reduce the demand through education. I think we can do it.

As pharmacists—the health professionals who possess the greates experise in drugs—we must not shirk our responsibilities to help counteract the continuing onslaught of illicit drug use. We have a thorough knowledge of the effects of drugs. We are accessible. We have respect and credibility in our communities.

All of us in the profession of pharmacy—practitioners, educators, industry personnel, students, scientists—have a role to play in trying to rid society of drug abuse problems.

OBLIGATION

As professionals who have gained much from society, don't we have an obligation to "put something back" that will help improve that society? Of course we do!

Perhaps each of us has an obligation to tithe a portion of time to fight drug abuse. Even if this tithing amounts to only a few hours per year per pharmacist, just think of how much could be accomplished through our collective efforts!

We pharmacists can by especially effective by visiting elementary schools and speaking to the children about the hazards of using drugs.

For pharmacists who want to get involved in drug abuse education, there are many sources to turn to for information and instructional materials. One of the most useful sources is an organization known as Pharmacists Against Drug Abuse or PADA.

PADA offers three items that you will find helpful: (1) *The Pharmacist's Guide to Drug Abuse,* a manual for pharmacists; (2) *The Kinds of Drugs Kids Are Getting Into,* a manual for parents; and (3) a speech kit for helping pharmacists make effective presentations in their communities.

TOLL-FREE

You may obtain these materials from PADA by phoning toll-free to 1-800-222-PADA.

Let us not lose sight of the fact that the fight against drug abuse must be waged as a full-scale war. We pharmacists are among the most important combatants in this war. *We* are the community drug experts with the know-how to educate children and parents.

Once we are properly deployed, we can be the secret weapon in this war—the secret weapon that will lead our society to victory!

I urge you to become involved! *Today!*

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Once again, Tom Gossel and Richard Wuest (shown) were popular speakers on "New Drug Updates" at the annual MPhA Mid Year Meeting held February 8, 1987 at the Annapolis Hilton Hotel. Over 100 Pharmacists attended.

ANNAPOLIS
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John Allan Lippert (left) received the Pharmacy Achievement Scholarship from the School of Pharmacy from Marvin Oed (right) at a ceremony during the Mid Year Luncheon.

The National Association of Retail Druggists hosted a strategy session with state association executives, chain executives and staff members of the National Association of Chain Drug Stores on the dispensing physician issue. Maryland was represented by MPhA Executive Director David Banta.

On January 18, 1987, the MPhA's Young Pharmacist Committee and the Alumni Association jointly sponsored a "Pharmacist Ski Weekend." A good turn-out, Lots of snow and plenty of fun were reported.

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The Compounders Corner

by
Loyd V. Allen, Jr., Ph.D., and M. Lou Stiles, M.S.
The University of Oklahoma College of Pharmacy
Oklahoma City, Oklahoma 73190

CARAFATE® IN ORABASE®

Rx	Carafate® 1 Gm Tablets	1
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PREPARATION:

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Carafate® (Sucralfate, Marion Laboratories, Inc.) is supplied in a 1 gram tablet which is employed for the short-term treatment of duodenal ulcers. The tablet also contains D&C Red #30 lake, FD&C Blue #1 lake, magnesium stearate, microcrystalline cellulose, and starch. The product is only minimally absorbed from the gastrointestinal tract and there are no known contraindications to the use of this drug.

Orabase® (E. R. Squibb & Sons, Inc.) is an ointment-type product containing pectin, gelatin, sodium carboxymethylcellulose, and plasticized hydrocarbon gel (a polyethylene and mineral oil gel base). This product is available plain, containing benzocaine, and containing Kenalog (triamcinolone). The product is used to provide a protective film in the oral cavity. It should not be rubbed. The instructions should read, ''Dab and gently press a thin film on the affected area as needed''.

SOURCE OF INGREDIENTS:

All these ingredients are commercially available. It should be noted that while Orabase® and Orabase® with Benzocaine are non-prescription products, Carafate® is a prescription item. Consequently, this preparation will require a prescription.

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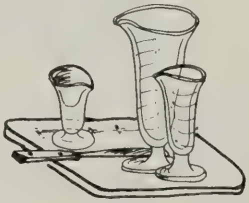

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

LETTERS

Dear Dave:

I am writing in response to the President's Message in the February, 1987 issue of the *Maryland Pharmacist*. As an H.M.O. pharmacist, I feel I must comment about the statement made by George Voxakis concerning dispensing H.M.O.s.

I believe that George and I share similar points of view concerning the serious issues facing our profession. I agree that dispensing is not an appropriate function for anyone without a pharmacist's or physician's license.

George indicates that technician dispensing is a growing phenomenon in H.M.O.s. I am aware of only three H.M.O.s in Maryland which operate pharmacies: The Johns Hopkins Health Plan, The Columbia Medical Plan, and Kaiser. All of these employ pharmacists to dispense at each pharmacy location. I am most certain that none of these allow technicians to dispense.

If an individual H.M.O. is handling drugs in an unprofessional manner, then let us focus on the source of this particular problem. Please do not implicate the practice of H.M.O. Pharmacy with general statements. Thank you.

Sincerely,
Richard W. Reitz, P.D.
Assistant Director

calendar

April 12 (sun)—Berman Seminar—CECC—Cardiovascular Therapy

April 29–May 2—NARD RX EXPO—NEW ORLEANS

April 30 (thurs)—Seminar: Chronic Care and the Elderly

May 17 (sun)—CECC—Arthritis

June 21–25—MPhA ANNUAL CONVENTION—SHERATON-BY-THE-OCEAN

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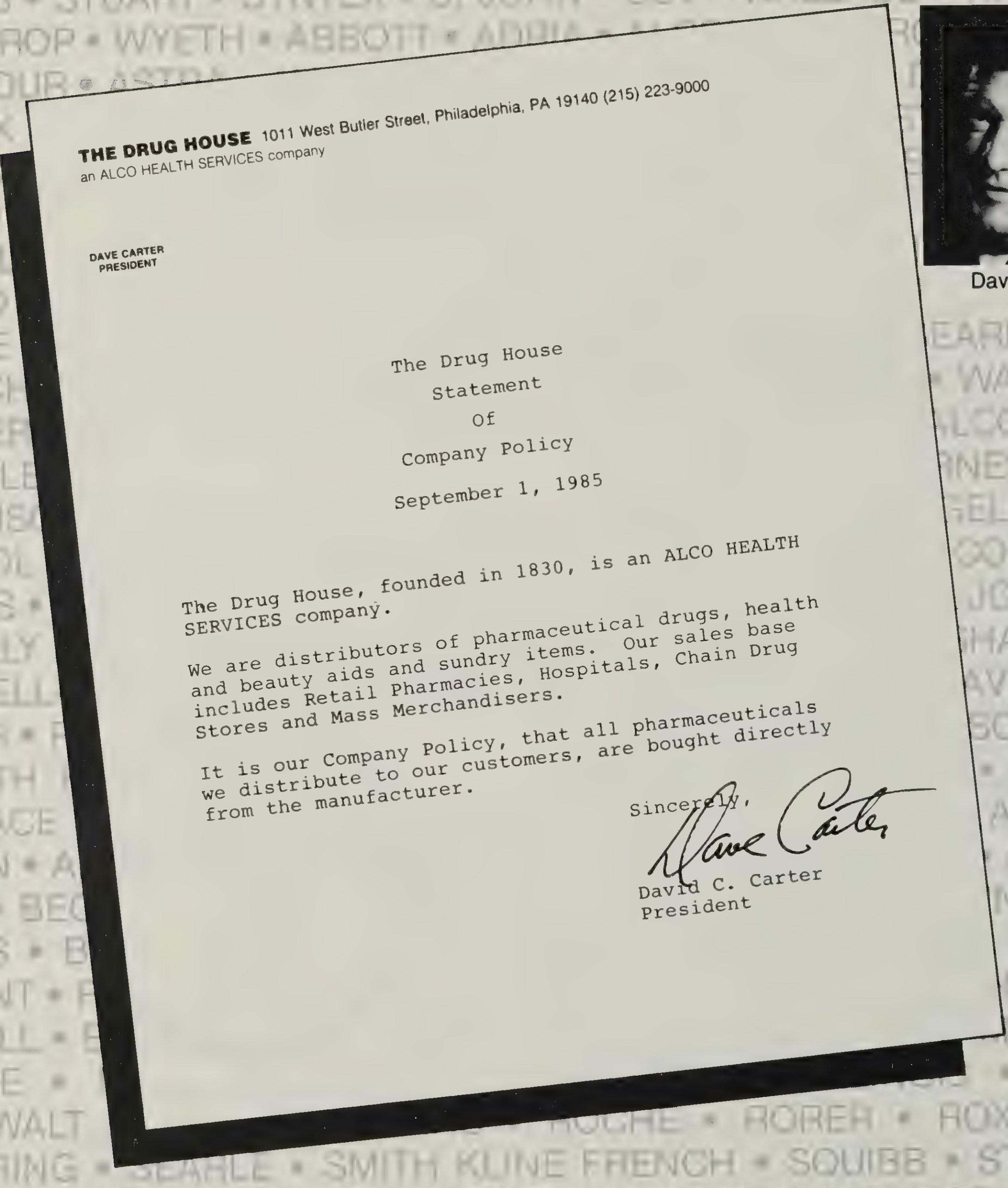

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Dave Carter

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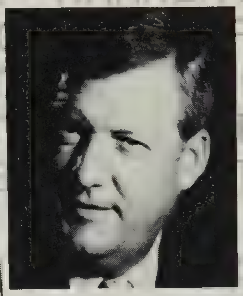

David C. Carter,
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The Future is Not What it Used to Be—Part II

— Peter P. Lamy

Hair Removal and OTC Depilatories

— J. Richard Wuest
— Thomas A. Gossel

Steroid Hormones
The Compounders Corner

— Loyd V. Allen, Jr.
— M. Lou Stiles

THE MARYLAND PHARMACIST

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MAY, 1987 VOL. 63 NO. 5

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Guest Message

President Voxakis has asked that I write a rare guest editorial from the Executive Director. I thought I would relate one of my favorite stories about mis-communications. It comes from a collection of *101 Zen stories,* transcribed by Nyogen Senzaki and Paul Reps and it is called “Trading Dialogue for Lodging.” It goes like this:

“Provided he makes and wins an argument about Buddism with those who live there, any wandering monk can remain in a Zen temple. If he is defeated, he has to move on.

In a temple in the northern part of Japan, two brother monks were dwelling together. The elder one was learned, but the younger one was stupid and had but one eye.

A wandering monk came and asked for lodging, properly challenging them to a debate about the sublime teaching. The elder brother, tired that day from much studying, told the younger one to take his place. ‘Go and request the dialogue in silence,’ he cautioned.

So the young monk and the stranger went to the shrine and sat down.

Shortly afterwards the traveler rose and went in to the elder brother and said: ‘Your young brother is a wonderful fellow. He defeated me.’

‘Relate the dialogue to me,’ said the elder one.

‘Well,’ explained the traveler, ‘first I held up one finger, representing Buddha, the enlightened one. So he held up two fingers signifying Buddha and his teaching. I held up three fingers, representing Buddha, his teaching and his followers, living the harmonious life. Then he shook his clenched fist in my face, indication that all three come from one realization. Thus he won and so I have no right to remain here.’ With this, the traveler left.

‘Where is that fellow?’ asked the younger one, running in to his elder brother.

‘I understand you won the debate.’

‘Won nothing. I'm going to beat him up.’

‘Tell me the subject of the debate,’ asked the elder one.

‘Why the minute he saw me, he held up one finger, insulting me by insinuating that I have only one eye. Since he was a stranger I thought I would be polite to him, so I held up two fingers congratulating him that he has two eyes. Then the impolite wretch held up three fingers, suggesting that between us we only have three eyes. So I got mad and started to punch him, but he ran out and that ended it!”

Obviously there is a lot of mis-communication in Pharmacy today. Sometimes it is easy to feel like the elder brother watching as various segments of our profession and ernest individuals attempt to convey meaning to one another. One of our greatest problems is the fragmentation of the profession which I sense is developing. While we diversify and expand the scope of care that falls under the definition of the practice of Pharmacy, we must be certain not to lose touch with each other. Let us accurately communicate.

David A. Banta, C.A.E.
Executive Director

P.S. I hope all members will have an opportunity to read Dr. Peter P. Lamy's excellent article on the Future of Pharmacy which concludes in this issue of *The Maryland Pharmacist*. The future really is not what it used to be! Keep communicating.

CONTINUING EDUCATION FOR PHARMACISTS

VOL. IV, NO. 4

Advising Consumers on Hair Removal and OTC Depilatories

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. review the physiology of hair growth;
2. explain the action, adverse effects, and limitations of OTC depilatories; and
3. discuss various methods of nonchemical hair removal.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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Objectives

At the conclusion of this article, participants should be able to:

1. state relevant points about the evolution of hair growth in humans;
2. list components of the physiology of hair growth that constitute its structure, stimulus for growth, and cycles for development;
3. define hirsutism and state its pathologic significance;
4. identify OTC depilatory ingredients and explain their mechanisms of action, adverse effects, major differences and precautions for use; and
5. define epilation and give examples of epilatory action.

Hair growth patterns are satisfactory to most persons, but sometimes there are problems. There are two major problems associated with hair growth: a lack of it in some areas, and unwanted hair growth in others.

A number of OTC remedies have been promoted over the years to enhance scalp hair growth. Although numerous claims have been made for them, an FDA/OTC panel could not find sufficient proof of effectiveness for their continued marketing. They were, therefore, placed in Category II, i.e., banned from future sale if FDA accepts the panel's recommendation.

The second concern is unwanted hair growth. There is proven clinical effectiveness for OTC depilatories indicated for removal of unwanted hair.

This article discusses important facts about the physiology of hair growth. It describes depilatory products, and reviews nonchemical methods for removing body hair.

Background

The desire to remove unwanted body hair is a relatively recent phenomenon. Body hair was, no doubt, important during past eons. It insulated against the cold and helped conserve body heat.

Early humans quickly learned how to clothe themselves with the hides of animals. Since the time man developed his "civilized" ways, body hair began losing its physiological function. It has now become almost vestigial.

Caucasians as a group have greater hair growth than Blacks. Orientals have the least body hair. Among Caucasians, those of Mediterranean and Near-East descent are hairier than those of Anglo-Saxon and Scandinavian ancestry.

Within any ethnic group, the extent of hair growth is familial, predominately controlled by the father. It is due to genetic differences in the responsiveness of hair follicles to stimulation by normal amounts of androgen. Even though androgen is the predominant male gonadal hormone, it is also produced by the adrenal glands and serves a number of important functions in both men and women.

The process of aging in women is also a factor in hair growth. As estrogen production diminishes, there is less counterbalancing of hair growth to androgenic stimulation than there was earlier in life. Therefore, facia and body hair growth tends to increase in geriatric women.

The History of Hair Removal Practices

In modern times, especially in th United States, good grooming practice dictates that women be free o hair growth on the legs and axilla (armpits) so that sheer hosiery an current fashions can be worn without "embarrassment."

But this is not a new social concept. Throughout history, a numbe of methods have been employed for removing unwanted hair. These have included singeing and applying derivatives obtained from various animal, vegetable, and mineral sources. Egyptian records dating 1500 years before Christ listed numerous recipes for such concoctions including burnt leaf of lotus in oil, and shell of tortoise with hippopotamus fat.

Other agents for removing unwanted hair included various salts of arsenic and thallium, leeches, ant's eggs, and blood from frogs, donkeys and pigs. Pumice stone and fine sandpaper were used to break-off hair buds. Thick syrups and molasses were popular for many years. These were applied to the skin, allowed to dry, and then stripped off along with clinging hair. A similar method is used in many modern beauty parlors, only hot wax is used instead.

Physiology of Hair Growth

Hair follicles cover the entire body surface of males and females except for the soles of the feet and the palms of the hands. Living cells that comprise these follicles die and become part of the hair shaft. As dead cells are added to the lower end of the shaft, hair is pushed upward to emerge above the skin surface. Hair growth rate exceeds that of all other tissues except for cells of the gastrointestinal tract and bone marrow.

Growth Cycles. Growth within any one hair shaft does not occur continuously. It proceeds in orderly cycles. In humans, these cycles occur randomly among the hair follicles.

Anagen. The period of active growth of mature hair is called anagen. Anagen may last two to six years or longer for hair on the scalp or beard, and six to twelve months for eyebrow, eyelash, trunk and leg hair. Approximately 85 to 95 percent of all hair follicles are in anagen at any time.

Catagen. Catagen is a temporary stage that follows. During catagen, the follicular cells shrink and ascend toward the skin's surface. This pushes the hair shaft ahead of them.

Telogen. This is followed by a third resting stage called telogen. Telogen occurs following mild trauma, such as vigorous brushing or shampooing. During telogen, hair is shed along with its root structure, characteristic of the catagen phase. This hair loss is compensated for by development of another follicle in anagen, which dislodges any remaining hair. The cycle then repeats.

Certain cytotoxic drugs induce hair loss by stimulating telogen development. Other drugs, such as minoxidil (Loniten®), are used investigationally to induce hair growth by reversing telogen or stimulating anagen.

Keratin and Hair. The characteristic physical appearance of hair is due to its keratin content. Seventeen percent of keratin is comprised of cystine, a sulfur-containing amino acid. Cystine is linked to other, non-sulfur-containing amino acids. These sulfur bridges confer various features of curliness, texture, and stability to the hair fiber.

A major problem in developing safe chemical depilatories is that skin keratin is similar in composition to that of hair. Chemical depilatories may not differentiate between the two.

Hair growth may be androgen-independent or androgen-dependent. **Androgen-independent** hair is usually vellus ("downy-like") hair. It is distributed evenly across the androgen-independent and androgen-dependent sites, and includes scalp hair, eyelashes, and eyebrows. It occurs in both men and women of all ages.

Androgen-dependent growth is referred to as "terminal" hair. It is restricted to androgen-responsive sites, such as the chin, chest and pubic areas. Transformation of vellus to terminal hair occurs primarily by stimulation from androgen, although the hormone is not absolutely necessary for this conversion.

Over the years, numerous attempts have been undertaken to stimulate hair growth by applying androgen. These trials have been unsuccessful. No quantity of androgen will stimulate hair growth in normal men. Drugs that have been reported to stimulate terminal hair growth are listed in Table 1.

Hirsutism

The term hirsutism essentially refers to excessive hair growth. But hirsutism should not be defined solely in terms of increased quantity of hair. It is better described as any amount of hair that develops in areas where it is cosmetically unacceptable to the individual. Hirsutism is normal and proper for individuals of some cultures; it is psychologically disturbing to others.

TABLE 1

Drugs Reported To Stimulate Hair Growth
Acetazolamide
Androgens
Corticosteroids (rarely)
Diazoxide
Minoxidil
19-Norprogestins
Penicillamine
Phenothiazines
Phenytoin
Streptomycin

Hirsutism *per se* is not a disease entity. Instead, it is a clinical symptom of another underlying cause. For example, it may signal a serious endocrinological disorder. Pathologic hirsutism in women usually results from excessive secretion of androgen from ovarian or adrenal cortical origin. Table 2 lists some of the pathological conditions that cause hirsutism.

Since hirsutism is linked to such a large variety of pathologic disorders, excessive hair growth occurring at abnormal sites should be investigated by a physician. Vellus hair that transforms excessively to terminal hair in an adult, or child before puberty, should also be brought to the attention of a physician.

TABLE 2

Potential Causes of Increased Hair Growth
Androgen-Dependent
Congenital adrenal hyperplasia
Cushing's syndrome
Hyperthecosis
Idiopathic hirsutism
Neoplasms of ovary or adrenal cortex
Polycystic ovarian disease
Androgen-Independent
Genetic disorders (e.g., congenital hypertrichosis)
Hypertrichosis lanuginosa
Juvenile myxedema
Porphyria cutanea tarda
Starvation (anorexia nervosa)

TABLE 3

Representative OTC Depilatory Products

Product	Manufacturer	Active Ingredient
Better Off Moisturizing Lotion	Dorothy Gray	Calcium thioglycolate
Magic Shaving Powder	Carson Products	Barium sulfide
Nair	Carter-Wallace	Calcium and sodium thioglycolate
Neet	Whitehall	Calcium thioglycolate
Nudit	Alleghany Pharmacal	Calcium thioglycolate
Nudit Depilatory Cold Wax Strips	Alleghany Pharmacal	Beeswax-rosin combination
Sally Hansen Facial Hair Removing Cream	Del Labs	Calcium thioglycolate
Zip Wax Hair Remover	Colorado Chemical	Beeswax-rosin combination

Depilatories

Depilatories destroy hair which is then wiped away. They can be used to remove hair on areas that are irritated by shaving, or on any area where shaving is not desirable.

Chemical depilatories should ideally be colorless, pleasantly perfumed, nonirritating, nonsensitizing and nonabsorbable. They should be easily applied, readily wet and adhere to the hair, and not stain skin or clothing. They should not dry on the skin because moisture is required for depilatory action. They should remove hair within five minutes of application and be easily removed by gentle wiping or rinsing with water.

There is no chemical depilatory that satisfies all of these criteria. Products containing calcium thioglycolate come the closest. Sodium thioglycolate, barium sulfide, and a beeswax-rosin combination are also used in OTC products. See Table 3.

Chemical depilatories are keratolytic. They destroy hair protein structure at the junction of the skin surface. Keratin is sensitive to highly alkaline pH, and readily degrades. Depilatories accomplish their lytic action by disrupting the disulfide bonds between cystine molecules in much the same manner as a heavy metal salt or alkali denatures protein. The osmotic pressure within the hair shaft increases; the hair swells and loses strength. It quickly deteriorates to an amorphous jelly-like consistency and can be removed by wiping the skin.

Chemical depilatories consist of two major chemical types. These include sulfide salts of barium, calcium, sodium or strontium; and calcium and sodium thioglycolate. Barium sulfide is an extremely effective depilatory. It is also more irritating to skin than calcium thioglycolate. It has an obnoxious odor because sulfide salts hydrolyze to hydrogen sulfide (sewer gas!). Although a less effective depilatory than sulfide salts, calcium thioglycolate is also less irritating to the skin and sense of smell.

Most people experience very little discomfort to calcium thioglycolate. Effects that have been reported include burning, erythema, rash, pruritus and stinging.

Products containing calcium thioglycolate and sulfide salts are buffered to pH 10 to 12.5. At a pH less than 10, depilatory action is slower and, therefore, skin keratin may be excessively irritated due to the length of time the drug must be left on the skin. An alkaline pH within the desired range also helps stabilize sulfide salts against hydrolysis to malodorous hydrogen sulfide.

Other Methods For Removing Unwanted Hair

There are several other methods for removing unwanted hair. The term epilation describes the removal of intact hair by uprooting.

Electrolysis. For permanent hair removal, the papilla must be destroyed. This can be achieved by electrolysis. In the procedure, a fine needle is inserted into the hair follicle down to the hair bulb. A mild electric current is applied and the papilla is destroyed.

Another method involves coagulating the papilla with high frequency alternating current electricity applied to the tip of the hair shaft. The current travels downward to the root where the papilla protein is coagulated.

Following either procedure, the hair is manually pulled out of the follicle. The coagulating method causes less irritation than the former since the skin is neither touched nor penetrated. However, it still may cause scarring when incorrectly performed.

Electrolytic hair removal, properly undertaken, is safe and permanent. But it is formidably slow and expensive. It may require two or more years before hair removal is complete since each hair has to be individually treated.

Hot Wax. The hot wax method of hair removal consists of applying a wax-rosin complex that has a low melting point in its molten form. This is allowed to dry and harden. It is then stripped off the area, sharply and firmly, against the direction of hair growth. When the wax is removed, it takes embedded hairs with it. Hot wax stripping is effective. It is also painful.

Plucking. Individual hairs can be plucked out. Plucking is satisfactory for removing a few hairs, but it is tedious and painful for clearing large areas. It can also result in infection o the follicle and scarring of the area While plucking may temporarily alleviate the problem, replacemen hair will begin to surface within three to six weeks. The painful process will then require repeating.

Shaving. Contrary to what many people believe, shaving does not stimulate hair growth. The growth rate temporarily accelerates immediately after shaving but this enhanced activity quickly reverses to normal While shaving is an effective means of removing hair from legs and underarms, it does pose problems in that it must be repeated frequently Cuts and scrapes are common i shaving is not carefully performed.

Consumer Advice

An OTC depilatory product can be recommended for most consumer who request one. They are safe and effective when used as directed.

Because each product has a distinct formulation, each has different directions for use. The length of time they must remain in contact with the hair is critical to maximize effectiveness and minimize skin irritation. The exact length depends on the nature of the active ingredient, and the composition of inactive components which influence parameters such as pH and surface tension.

After the depilatory has remained on the skin for the prescribed period of time, it should be removed by scraping with a blunt edge of a spatula or moistened wood tongue depressor. Smooth strokes that do not scrape the skin are best.

Because of their alkaline pH, depilatories are extremely irritating to mucous membranes. They should, therefore, not be used around the eyes or mouth, or on inflamed, irritated or abraded skin. They should not be used on breast nipples or around the genitalia.

Consumers should be advised to not apply a depilatory to the skin immediately after antiperspirant application or following shaving. Similarly, colognes and other cosmetics must not be applied shortly after a depilatory has been used. Doing so may cause intense irritation and inflammation.

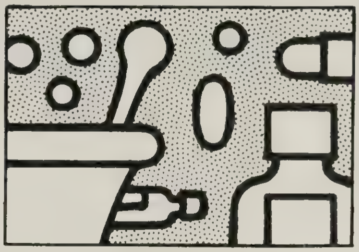
Patient Aid

The aid is designed for distribution to patients as a ''package stuffer'' or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other message, place such information so that it covers the artwork in the upper right-hand corner.

Clip and Save

Things You Should Know FOR YOUR GOOD HEALTH



The Facts of Life

As we grow older, numerous ailments begin to afflict our bodies. Various diseases present a wide range of symptoms which make us aware that something is wrong.

Constipation is a very common symptom, which occurs frequently in older adults. Like a fever, it can be caused by many different conditions. Constipation is defined as the infrequent and difficult passage of stool. Among normal, healthy people the frequency of bowel movement varies greatly, ranging from three movements a day to three a week. As a rule, if more than three days pass without a bowel movement, the intestinal contents may harden and a person may have difficulty or pain during elimination.

Many misconceptions exist concerning proper bowel habits. One such fallacy is that you must have a bowel movement every day in order to be normal. As mentioned above there is a wide range of variations among people. You must know what is normal for you.

Such misconceptions have led to significant overuse and abuse of laxatives. Often they are not needed and may be harmful. Most people have experienced an occasional bout of constipation that has corrected itself with diet and time. The following is a list of some of the most common causes:

Poor Diet. Low-fiber and highly refined foods like pastries, candy, cheese, white bread, and many snack foods may lead to constipation. Recent studies have indicated that high-fiber diets (whole grain cereals and breads, vegetables, fruits) result in larger stools, more frequent bowel movements, and as a result, less constipation.

Irritable Bowel Syndrome. A condition also referred to as "spastic colon." Spasms of the colon delay the speed with which the contents of the intestine move through the digestive tract, thereby leading to constipation.

Psychological Constipation. This is very common, and results from misconceptions about what is normal and what is not. This condition can be corrected by proper patient education if recognized early enough.

Laxative Abuse. Laxative dependency can result from habitual use. This abuse leads to increased dosages over a period of time. Eventually the intestine becomes insensitive and fails to work properly.

Medications. A side effect of certain medications is constipation. Some of these prescription and over-the-counter medications include: narcotic pain medications, antacids which contain aluminum, antispasmodic drugs, antidepressant drugs, tranquilizers, iron supplements and anticonvulsant medications. Consult your pharmacist for specific medication names.

Travel. A change in environment may relate to changes in diet, schedule and drinking water, all resulting in changes in bowel movements.

Pregnancy. The pressure of the heavy womb compresses the intestine resulting in decreased motility. Hormonal changes and decreased physical activity during pregnancy also may be causes of constipation.

Prior to using a laxative preparation *ASK YOUR PHARMACIST* about the best medication or alternative for you.

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Please see next page for brief summary.

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2454-11-86

NEW...ONCE DAILY IN MILD TO MODERATE HYPERTENSION

Brief Summary

ISOPTIN® SR
(verapamil HCl/Knoll)
240 mg scored, sustained-release tablets

CONTRAINDICATIONS: 1) Severe left ventricular dysfunction (see WARNINGS), 2) Hypotension (less than 90 mmHg systolic pressure) or cardiogenic shock, 3) Sick sinus syndrome or 2nd or 3rd degree AV block (except in patients with a functioning artificial ventricular pacemaker).

WARNINGS: Heart Failure: ISOPTIN should be avoided in patients with severe left ventricular dysfunction (see DRUG INTERACTIONS). Patients with milder ventricular dysfunction should, if possible, be controlled before verapamil treatment. Hypotension: ISOPTIN (verapamil HCl) may produce occasional symptomatic hypotension. Elevated Liver Enzymes: Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Periodic monitoring of liver function in patients receiving verapamil is therefore prudent. Accessory Bypass Tract (Wolff-Parkinson-White): Patients with paroxysmal and/or chronic atrial flutter or atrial fibrillation and a coexisting accessory AV pathway have developed increased antegrade conduction across the accessory pathway producing a very rapid ventricular response or ventricular fibrillation after receiving intravenous verapamil. While this has not been reported with oral verapamil, it should be considered a potential risk. Treatment is usually D.C.-cardioversion. Atrioventricular Block: The effect of verapamil on AV conduction and the SA node may cause asymptomatic 1st degree AV block and transient bradycardia. Higher degrees of AV block, while infrequent (0.8%), may require a reduction in dosage or, in rare instances, discontinuation of verapamil HCl. Patients with Hypertrophic Cardiomyopathy (IHSS): Although verapamil has been used in the therapy of patients with IHSS, severe cardiovascular decompensation and death have been noted in this patient population.

PRECAUTIONS: Impaired Hepatic or Renal Function: Verapamil is highly metabolized by the liver with about 70% of an administered dose excreted in the urine. In patients with impaired hepatic or renal function verapamil should be administered cautiously and the patients monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacological effects (see OVERDOSAGE).

Drug Interactions: Beta Blockers: Concomitant use of ISOPTIN and oral beta-adrenergic blocking agents may be beneficial in certain patients with chronic stable angina or hypertension, but available information is not sufficient to predict with confidence the effects of concurrent treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities. Digitalis: Clinical use of verapamil in digitalized patients has shown the combination to be well tolerated if digoxin doses are properly adjusted. However, chronic verapamil treatment increases serum digoxin levels by 50 to 75% during the first week of therapy and this can result in digitalis toxicity. Upon discontinuation of ISOPTIN (verapamil HCl), the patient should be reassessed to avoid underdigitalization. Antihypertensive Agents: Verapamil administered concomitantly with oral antihypertensive agents (e.g., vasodilators, angiotensin-converting enzyme inhibitors, diuretics, beta blockers, prazosin) will usually have an additive effect on lowering blood pressure. Patients receiving these combinations should be appropriately monitored. Disopyramide: Disopyramide should not be administered within 48 hours before or 24 hours after verapamil administration. Quinidine: In patients with hypertrophic cardiomyopathy (IHSS), concomitant use of verapamil and quinidine resulted in significant hypotension. There has been a report of increased quinidine levels during verapamil therapy. Nitrates: The pharmacologic profile of verapamil and nitrates as well as clinical experience suggest beneficial interactions. Cimetidine: Two clinical trials have shown a lack of significant verapamil interaction with cimetidine. A third study showed cimetidine reduced verapamil clearance and increased elimination to 1/2. Anesthetic Agents: Verapamil may potentiate the activity of neuromuscular blocking agents and inhalation anesthetics. Carbamazepine: Verapamil may increase carbamazepine concentrations during combined therapy. Rifampin: Therapy with rifampin may markedly reduce oral verapamil bioavailability. Lithium: Verapamil may lower lithium levels in patient on chronic oral lithium therapy. Carcinogenesis, Mutagenesis, Impairment of Fertility: There was no evidence of a carcinogenic potential of verapamil administered to rats for two years. Verapamil was not mutagenic in the Ames test. Studies in female rats did not show impaired fertility. Effects on male fertility have not been determined. Pregnancy (Category C): There are no adequate and well-controlled studies in pregnant women. ISOPTIN crosses the placental barrier and can be detected in umbilical vein blood at delivery. This drug should be used during pregnancy, labor, and delivery, only if clearly needed. Nursing Mothers: ISOPTIN is excreted in human milk, therefore, nursing should be discontinued while verapamil is administered. Pediatric Use: Safety and efficacy of ISOPTIN in children below the age of 18 years have not been established.

ADVERSE REACTIONS: Constipation 8.4%, dizziness 3.5%, nausea 2.7%, hypotension 2.5%, edema 2.1%, headache 1.9%, CHF/pulmonary edema 1.8%, fatigue 1.7%, bradycardia 1.4%, 3° AV block 0.8%, flushing 0.1%, elevated liver enzymes (see WARNINGS). The following reactions, reported in less than 1.0% of patients, occurred under conditions (open trials, marketing experience) where a causal relationship is uncertain; they are mentioned to alert the physician to a possible relationship: angina pectoris, arthralgia and rash, AV block, blurred vision, cerebrovascular accident, chest pain, claudication, confusion, diarrhea, dry mouth, dyspnea, ecchymosis or bruising, equilibrium disorders, exanthema, gastrointestinal distress, gingival hyperplasia, gynecomastia, hair loss, hyperkeratosis, impotence, increased urination, insomnia, macules, muscle cramps, myocardial infarction, palpitations, paresthesia, psychotic symptoms, purpura (vasculitis), shakiness, somnolence, spotty menstruation, sweating, syncope, urticaria. Treatment of Acute Cardiovascular Adverse Reactions: Whenever severe hypotension or complete AV block occur following oral administration of verapamil, the appropriate emergency measures should be applied immediately, e.g., intravenously administered isoproterenol HCl, levarterenol bitartrate, atropine (all in the usual doses), or calcium gluconate (10% solution). If further support is necessary, inotropic agents (dopamine or dobutamine) may be administered. Actual treatment and dosage should depend on the severity and the clinical situation and the judgment and experience of the treating physician.

OVERDOSAGE: Treatment of overdosage should be supportive. Beta-adrenergic stimulation or parenteral administration of calcium solutions may increase calcium ion flux across the slow channel, and have been used effectively in treatment of deliberate overdosage with verapamil. Clinically significant hypotensive reactions or fixed high degree AV block should be treated with vasopressor agents or cardiac pacing, respectively. Asystole should be handled by the usual measures including cardiopulmonary resuscitation.

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Featured Article

The Future is not What it Used To Be

by Peter P. Lamy, PhD

Part II
Continued from April, 1987 issue

Changes Directly Affecting Traditional Pharmacy

Employment: Employment statistics (Table XIII) indicate that chain pharmacies are becoming the largest employer of recent graduates, although there are predictions that there will be an increased need for hospital pharmacists and consultant pharmacists in the long-term care sector.

By 1995, according to Arthur D. Little, half of the U.S. population will obtain health care from managed care systems, such as HMOs and PPOs. Patients will have to obtain their medications from pharmacies with contractural agreements with these systems, and independent pharmacies may be the big losers.

Mail Order: Mail order prescriptions still make up only a very small percentage of all prescriptions. AARP, the nation's largest mail-order service, now fills approximately 7 million Rx/year. However, that number may grow fast. Blue Cross/Blue Shield has decided to provide mail order prescriptions for all federal employees, the plan to be implemented by 1987. It will cover more than 1 million families. A $5 co-pay will permit people to enter the program. Medco Containment has just won a mail-order contract with 40 companies, unions, and HMOs, covering more than 5 million people.

Attempts have been made to curb the spread of mail-order services, by citing the need to counsel patients. However, the Attorney General of Utah has just ruled that written instructions accompanying the mailed prescription will satisfy that requirement.

An interesting study has been reported by Pharmaceutical Card System, Inc (PCS), a Phoenix, Arizona-based third party administrator, providing reimbursement to providers of prescription drugs. The study has shown that mail-order service is not necessarily cost-effective. Over-utilization and waste are two major problems. Another is switching. Clinical response to a given NSAID, for example, varies markedly among patients who appear to have the same condition (rheumatoid arthritis or osteoarthritis). In California, 69.1% of RA patients were switched from one NSAID to another. Patterns of switching were unpredictable and RA patients had an average of 2.3 switches over six quarters. Thus, PCS concluded that there may be potentially large savings for certain classes of drugs, but currently total costs for mail-order service compared to another plan providing prescriptions are higher, particularly when the consumer is elderly.

Physician Dispensing: Pharmacists want to prescribe, physicians want to dispense. Physicians are starting to dispense "commonly prescribed" drugs in their own office and some hospitals are beginning to use the pre-packaged drugs in their ambulatory care centers and emergency rooms. Physician's Pharmaceutical Services (PPS) has recently signed an agreement with Humana to supply pharmaceuticals to Humana's 125 Med-First primary care centers. While Pharmacy decries the loss of "checks and balances", physicians are told of the many patient benefits that direct dispensing provides and, incidentally, of the financial benefits (up to $30,000/year from the dispensing fee). There are now 25 companies specializing in providing pre-packaged medications to physicians. Physician dispensing still accounts for only a very small fraction of the $20 billion prescription drug market, but, while estimates vary widely, it could reach $10 billion. While only one to five percent of physicians now dispense, that number could easily double in the near future. Direct dispensing is illegal only in very few states, i.e. Arkansas, Massachusetts, Texas, and Utah.

TABLE 13
Employment of Recent Graduates

	Chain Pharmacies	Hospital Pharmacies
1984	32.0%	26.1%
1985	34.7%	25.9%
1986	38.8%	24.2%

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, Chairman, Department of Pharmacy Practice and Administrative Science, School of Pharmacy and Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD 21201

The Scrip: Medicost insures the drug benefits for Ford hourly workers and retirees in Michigan and Chrysler salaried workers and retirees in southeastern Michigan. Medicost pays independent and small-chain pharmacy providers with a voucher (scrip), covering the drug ingredient, a $1.50 fee, and 15 cents for the container. The Pharmacy is then obliged to use the scrip to purchase drugs from a designated wholesaler. The only cash that enters into the transaction is the $2 co-pay from the patient. Larger chains are still paid by check as usual.

Generics: The hospital's drug budget and the drug budget of managed care plans have experienced disproportionally large increases. Rx inflation exceeds the medical CPI, which, in turn, exceeds the CPI. Prescription drug costs account for five to 10% of corporate health plan expenses, a major target for cost containment. The use of generics will increase, and may increase by as much as 15%. But, while the cost for generic drugs decrease, the cost for single-source drugs continue to increase dramatically, possibly by 10%/ year. Often, and unreasonably, pharmacists are held responsible for these increases.

Therapeutic Substitution: As a cost containment measure, hospitals have long practiced therapeutic substitution, under the guidance of the Pharmacy and Therapeutics Committee. Indeed, therapeutic substitution is thought to occur in 50% of community hospitals as well as in an increasing number of "managed" health care delivery systems. It is viewed by some as a major cost containment measure that will surely find application in the community pharmacy, and by others as a broader losening of the physician's prescribing authority than that which occurred when generic substitution began. Some concerns have been raised that pharmacists would either not have access to the necessary patient data or would be unprepared to deal with and interpret correctly patient data to make substitutions in a manner that would not increase the risk to the patient.

New Dosage Forms: IMS has predicted that the world pharmaceutical market will grow from $74 billion today to $116 billion in 1990. The US is projected to rank first in sales. One cannot assume, though, that this will result in an increased number of prescriptions. Indeed, major changes could occur soon in the traditional prescription market, brought about by new dosage forms. New dosage forms provide means of targeting drugs to disease sites, increasing effectiveness and decreasing toxicity. Drugs packaged in liposomes, transdermal patches, nasal sprays, polymers, implants and monoclonal antibodies will undoubtedly revolutionize pharmacy. It is likely that in 20 years, 40% of all drugs sold will be in the form of new delivery systems. These will have major implications for the treatment of cancer, cardiac problems, diabetes, inflammation, infections, and in pain control. Aside from the new dosage forms, there will be more genetically engineered products, such as human insulin, growth hormone, interferon, and interleukin-2. Actual and potentially injectable particulate systems include polymeric carriers, microspheres, nanoparticles, and liposomes. These delivery systems may be used to encapsulate interferons, DNA-containing plasmids, interleukin, enzymes, hormones, and clotting factors. Particulate carriers include micro- and nano particles, which can be composed of proteins, sugars, or synthetic polymers, as well as liposomes. Polymeric carrier systems include methacrylamide polymers and cyclodextrin. Drug-polymer microcapsules may be useful in chemotherapy and long-term delivery of cardiac medication. A new biodegradable polymer insulin-releasing system is being developed. Insulin would be implanted in the polymer, injected into the body, and released by an externally activated ultra-sound pulse system. These dosage forms would have to be administered once and in lower dosage over a prolonged period of time.

Implants would work in a similar manner. The Programmable Implantable Medication System (PIMS), about the size of a hockey puck, encased in a titanium shell, holds a three month supply of insulin. It is implanted into the abdomen. It is refilled in the physician's office. Monoclonal antibodies reached sales of $155 million in 1985 and may reach sales of $4.1 billion in 1995. Their main use is in diagnostic test kits.

On the other hand, there may be more oral controlled release drugs, transdermal patches, and buccal delivery systems. Polymer coating on oral tablets may allow oral administration of some drugs currently delivered by injection, such as vaccines, analgesics and insulin. The OROS system, after a shaky start, will make heavy inroads, as this delivery system is not affected by the gastrointestinal pH.

Non-Prescription Drugs: The rate of conversion of drugs from Rx status to non-prescription status is increasing. Some drugs have achieved a 400% increase in sales after achieving nonprescription status. Of concern to pharmacists should be the fact that less than 50% of all OTC drugs are sold in pharmacies. As the home care market develops, it will develop into an essentially provider-assisted self-care sector. Drugs such as cimetidine, hydrochlorthiazide, and propranolol are scheduled to achieve OTC status (cimetidine possibly by 1990) and it is imperative that pharmacists strongly reach out for this market.

Pharmacy Opportunities in the Changing System

As large health care providers, hospitals, and physicians come to terms with cost containment, quality of care, technology needs, high tech and low tech care delivery, marketing efforts and joint ventures, pharmacy and pharmacists must re-define their role. Perhaps, mega-corporations and managed systems will bring about similar responses from pharmacy. Change is needed. With a fixed stare, Pharmacy and its practitioners have looked at and debated areas of non-reimbursement (does a service cost money or provide income?) diminishing reimbursement under third-party systems, co-pay, and many other financial issues, such as incentives to dispense generics. As is so often the case, during those discussions, the practice may disappear.

Clearly, pharmacy's contribution, its essential contribution, to the emerging health care sector will be in the areas of information and consultation. Pharmacists, already expert in the use of computers, will be utilizing systems which will permit them to act as consultants to providers and patients. Pharmacists will become expert in life-sustaining technology and in patient identification. For example, urinary incontinence is a disorder leading to significant morbidity and even mortality, all too often unrecognized or neglected. The highest incidence is among patients with cognitive disorders and impaired motility.

Postural instability and falling is probably much higher than is indicated by the number of fractures reported. The vast majority of elderly who fall do not sustain fractures, but fall repeatedly. Twenty percent of the elderly on digoxin are thought to be digoxin-toxic, which can only be positively identified by close observation of the patient. The early signs of tardive dyskinesia can also be recognized by close patient observation. As has been shown by the large study in Liverpool, adverse drug reactions can often be avoided by selection of an alternate drug that the patient can tolerate. Pharmacists, expert in pharmacotherapy, must assume that consultative role.

TABLE 15
Suggested Guideline for Drug Use in Chronic Disease Management

AIM	for "care" not "cure"
MANAGE	disease and problems
MAXIMIZE	functional status and quality of life
PRESERVE	mental status mobility continence nutritional status
REMEMBER	chronic care is constantly changing care

Pharmacy also needs to recognize and work more closely with its many friends in other fields of health care. HHS Secretary Bowen has proposed that the drug regimen review, which pharmacists have performed in SNFs since 1974 under a mandate by the federal government and which has been found both cost-effective and clinically effective by the Comptroller General, could be performed by either pharmacists or nurses. Among the many non-pharmacist organizations opposing this suggestion is the American Association of Homes for the Aging (AAHA), which argued that the complexity of medication combinations require a pharmacist who is trained to recognize the interactive effects of multiple and complex drugs. Indeed, buttressed by such support, pharmacists must reach out and seek the same mandate for the home care patient. One of the major reasons for adverse drug effects among community-living long-term care patients is the lack of supervision of drugs and monitoring of drug effects.

Pharmacists must seek to fulfill a number of social

TABLE 14
Pharmacy in Long-Term Care*

Home Care, Level I	**Pharmacist's Services**
Well, ambulatory elderly	Drugs, education, monitoring, preventive care, nutritional advice, referrals, consumer education, provision of special packaging for medication
Housebound with activity limitations, but relatively well	More intensive monitoring, review, special educational counseling, follow-up. "At Risk" Patient Medication Record.
Level II	
Ambulatory, Chronic care with multiple diseases and disabilities	Home health care provision TPN, enteral therapy, oxygen, DME
Level III	
Day care center patients	Coordinate ancillary home care (housekeeping, nursing, PT, etc.)
Level IV	
Homebound, dependent	Consistent monitoring, counseling and follow-up to patient, family, physician and other providers

Adapted from: Lamy PP: Am J Pharm Edu, 45:391, 1981
* Services for each level of care are built on services offered in the less serious level of care

TABLE 16
The Chronic Use of Drugs

1. Overall morbidity/mortability of disease process is decreased by the drug.
2. There is no substantial toxicity.
3. The beneficial effects of drug therapy are not outweighed by side effects.

TABLE 17
An Approach to Minimize Hazard of Drugs

Patient Considerations	**Drug Considerations**
Is drug or non-drug therapy better for patient?	Is drug necessary? What dose? Which dosage form?
Is patient impaired mentally, physically, financially? Is patient literacy-impaired?	What are drug's anticipated a. Therapeutic effects b. Side effects
Is patient sensory impaired?	Will drug interfere with intercurrent disease? Existing drug regimen?
Can patient administer dosage form selected?	Is drug affordable?
Does patient live alone?	Can drug be self-administered?
How many physicians does patient consult?	Can drug be stopped? When? How?

responsibilities in the community. For example, the National Council of Senior Citizens has estimated that nearly 5.7 million people aged 65 and over, 21% of the elderly population, "may be at nutritional risk" because they have incomes below 125% of the poverty line. Pharmacists should seek to become nutritional experts, not simply dispensers of vitamins, minerals, and nutritional supplements. Pharmacists, as health care providers, must become more familiar with health fraud, and advise their patients in this important area. In the early 1960s, the nation's health fraud toll was estimated to be about $1 billion yearly. Later, that estimate was doubled and in 1984, Rep. Claude Pepper reported that health frauds cost elderly Americans $10 billion annually. Victor Herbert testified that Americans spend as much as $26 billion each year on alternative, unproven forms of health care.

Pharmacists must take a more active role in quality-of-care issues. They should be ready to consult with providers and patients now on the role of diuretics in the management of hypertension. Is use of diuretics in hypovolemic patients, susceptible to hypokalemia, justified? On the other hand, is a switch to more costly drugs, such as beta blockers, calcium channel blockers, or ACE-inhibitors justified when it could add $1 billion a year to US drug expenditures?

Pharmacists routinely monitor drug therapy of selected groups of patients in 65% of the large hospitals and 40% of small hospitals, but only 10% of the large hospitals offer a full range of clinical services. Here is clearly an area that merits more attention.

A major opportunity exists in the quality-of-care arena with the changing view of drug utilization review. It is almost certain that retrospective reviews will no longer be acceptable and that criteria-based, prospective on-going utilization review procedures will be used. While the responsibility in the new JCAH guidelines are assigned to the medical staff, pharmacists will find that well-organized and planned programs by pharmacy will most likely be welcomed with open arms.

Recognizing the changing needs, one can develop a list of proposed functions for Pharmacy and pharmacists. Tables XIV to XVII propose pharmacist functions for the long-term care sector.

Then, importantly, there is "the other drug problem", so identified by FDA Commissioner Young and HHS Assistant Secretary Windom. They have coined this term and applied it to the "very costly misuse, poor use, or non-use of prescription drugs." They report that of 1.6 billion Rx/year, 800 million may be taken incorrectly.

Pharmacy certainly has a major role to play. To begin with, it must learn that the compliance principles applied to acute care will not work in long-term care. Pharmacists must learn that elderly patients, in particular, often have different goals than the provider may have. Tomorrow's well-being, i.e. the elimination of GI upset, blurred vision, or whatever, so that one can enjoy a scheduled event, is often more important than long-term danger. Patients have been identified as "capricious non-compliers" and "intelligent non-compliers", and we ought to listen to them more closely. Patients are needed as "therapist-aide", bringing and receiving information. Recently, patients have been classified in four different categories (Table XVIII). Pharmacists must be familiar with the major reasons for ineffective communications (Table XIX) and factors that may increase the risk of non-compliance (Table XX). Most importantly, pharmacists need to recognize that "compliance" is an outdated concept, particularly in long-term care. In the fast-developing home care sector, it is often the caregiver who will act for the homebound patient, needing to learn about drugs, drug administration, and observation of drug effects and, most importantly, the need to communicate. There must be "agreement" between provider and consumer.

TABLE 18
Health Care Consumer Classification*

Consumer	Description
No Time for Health	5% of population. Don't like to spend time or money on health care.
Tell Me What To Do	43% of population. Have some unhealthy habits. Look to physician to make all decisions.
Good Patient	36%. Older. Many women. Exercise, loyal to physician, conscious of healthy habits
Avid Partners	15%. Highest income & education. Exercise regularly. View physician as equal partner.

* Based on quality, fitness, loyalty, personal involvement, stress, and self-diagnosis. Endresen Research, Seattle

TABLE 19
Major Reasons for Ineffective Communications with Patient

Attitudinal Factors:	Lack of motivation, poor health beliefs
Knowledge Factors:	Unsure of purpose of desired outcome, necessary length of therapy dosage, administration times. Lack of warnings and information on side effects.
Social Factors:	Isolation, lack of support system, difficulty in coping, lack of regular supervision.
Behavioral Factors:	Capricious non-response. "Intelligent" selection of certain communicated factors.
Patient Status:	
a. Age	Geriatric
b. Functional	Disability, physical impairment, sensory impairment (visual, auditory, tactile), dependency, literacy (inability to read or understand english language).
c. Mental	Mental impairment (anxiety, confusion, dementia, depression), post-illness asthenia.
Drug Factors:	Multiple regimens with multiple administration times, side effects, oversedation, cognitive impairment

TABLE 20
Factors Increasing Risk of Noncompliance

- Mental impairment
- Physical impairment
- Sensory impairment
- Advanced age
- Multiple drug regimens
- Drugs causing cognitive impairment

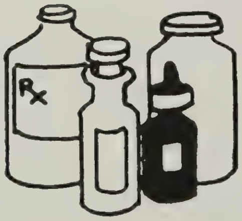
This kind of approach is even more important in view of the increasing availability and use of non-prescription drugs. OTC drugs. OTC drugs already account for 40% of all drugs used in skilled nursing facilities, and will most likely achieve the same or an even higher percentage in the home care sector. Close interaction between pharmacist and caregiver/consumer is then obviously mandatory. Methodologies which could improve patient cooperation and/or provider-assisted self-care are given in Table XXI.

TABLE 21
Improving Provider-Assisted Long-Term Self Care

1. Establish partnership-like relation and trust
2. Direct efforts towards enabling factors and good information base
3. Use cues
   a. Tailor drug administration to activities of daily living
4. Use reminders
   a. Stress importance of provider-assisted self-care of every visit
5. Follow-up
   a. Call if drug refill is missed
   b. Vary number of contacts directly with degree of cooperation
6. Use Rewards
   a. Recognize patient effort, progress
7. Achieve social support
   a. Involve family caregiver

SUMMARY

Major changes in the health care system, current and future, will bring about major changes in the practice of pharmacy. These changes unquestionably present a clear and present danger to the traditional delivery of pharmacy services, but they also present a clear and present opportunity for pharmacy to achieve an even greater role in the provision of health care than ever before.



LETTERS

Dear David,

The Maryland Society of Hospital Pharmacists (MSHP) requests your assistance in publicizing our annual seminar for 1987 in The Maryland Pharmacist Publications. See below our specifics:

Title: "Infectious Diseases: A Broad Spectrum Approach."

Sponsor: Maryland Society of Hospital Pharmacist-annual seminar committee

Date: October 9, 10, and 11th. (To take advantage of lower postsummer rates and cooler but wonderful fall weather of Virginia.)

Place: The Williamsburg Hilton and National Conference Center, 50 Kingsmill Road, Williamsburg Virginia 23185. (804) 220-3500.

Contact Person: MSHP seminar committee chairman, Mr. Richard Pollhammer, Department of Pharmacy Services, Johns Hopkins Hospital, 600 North Wolfe St., Baltimore, Maryland 21205 (301) 955-6591.

Topics: Will include a broad spectrum of topics on antibiotic therapy, including: sexually transmitted diseases, a poster session, institutionally acquired infections, and other resistant infections.

Free time: there will be ample time to explore the Williamsburg area, including; Colonial Williamsburg (trace the footsteps of T. Jefferson, P. Henry, and other founding fathers), Busch Gardens Ammusement Park, nearby Yorktown (1st permanent English settlement ca. 1607), shops for antiques, handicrafts, pottery, candles, and other interesting things and souveniers.

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Thank you

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Secretary of MSHP annual seminar committee
for publication.

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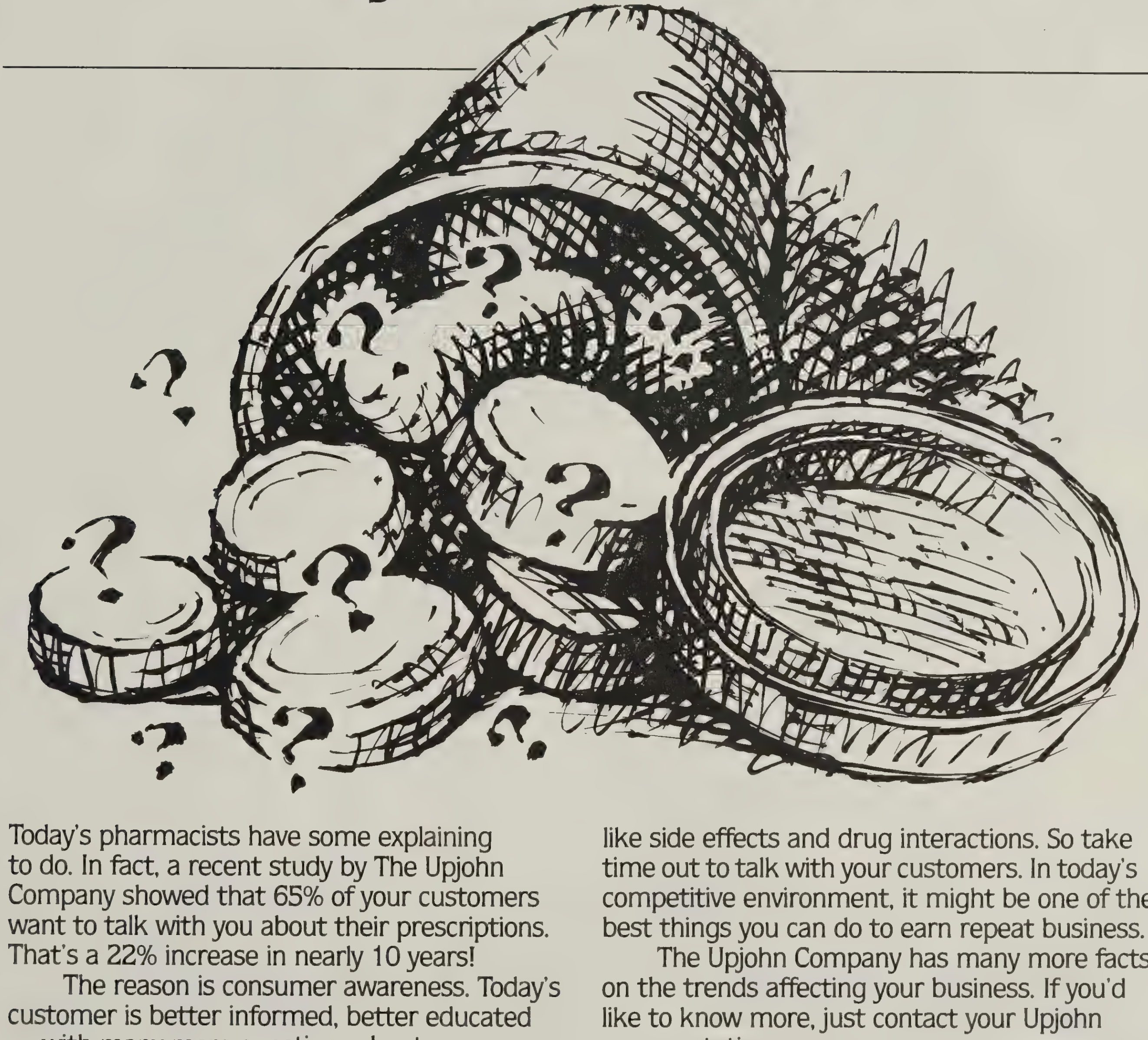

Today's pharmacists have some explaining to do. In fact, a recent study by The Upjohn Company showed that 65% of your customers want to talk with you about their prescriptions. That's a 22% increase in nearly 10 years!

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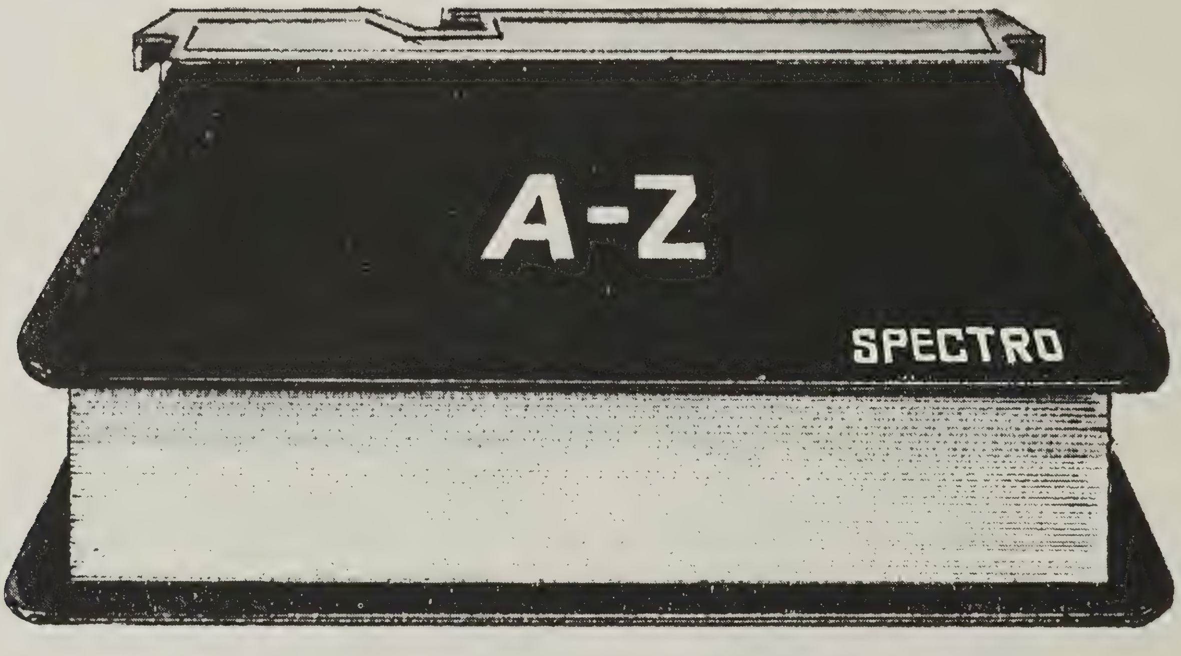

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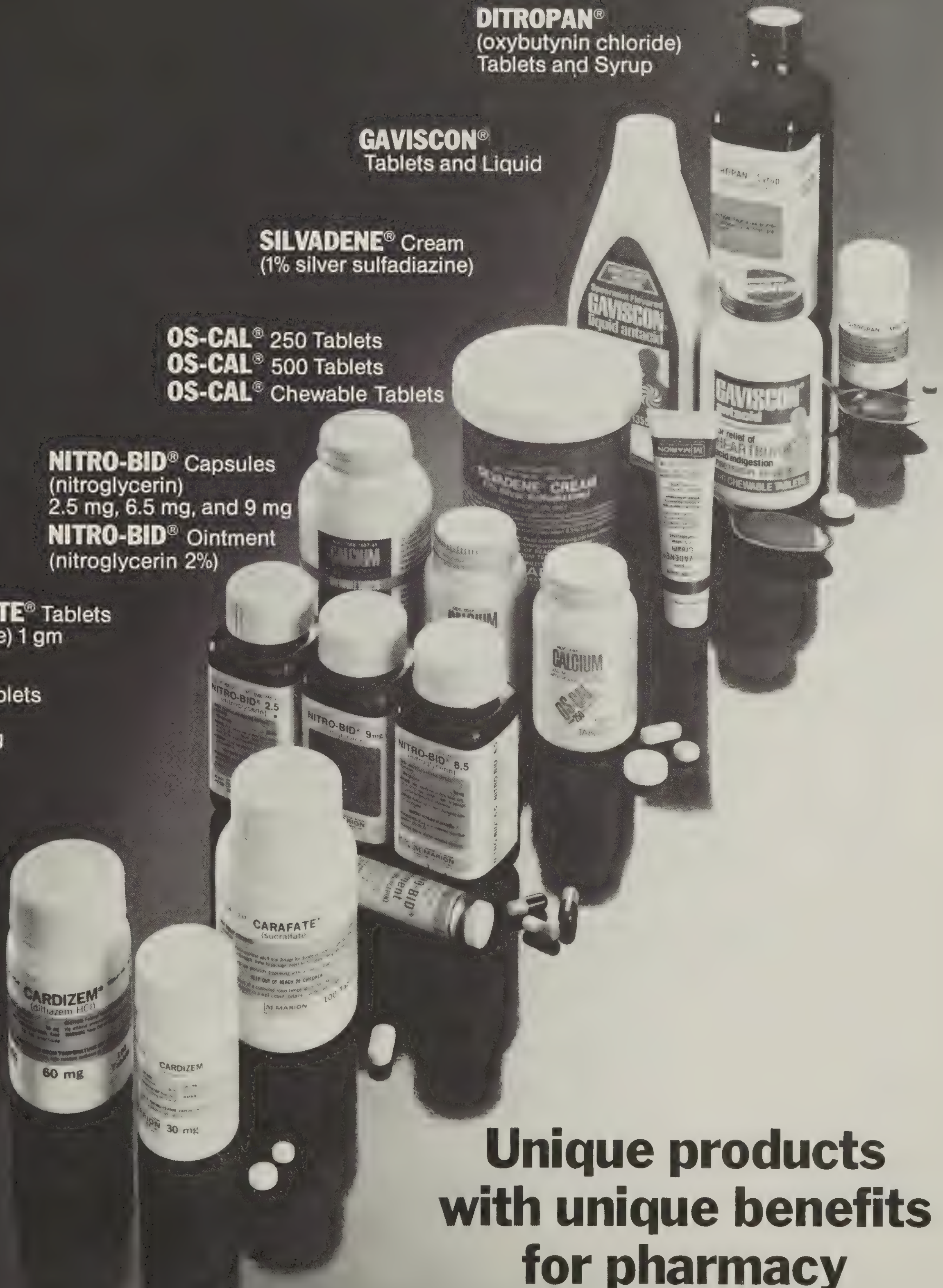
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Facts About High Blood Pressure in America

Prevalence Data

Approximately **58 million** Americans have an increased risk of illness and early death due to high blood pressure. This represents more than **one out of every four** adult Americans.

Anybody can have high blood pressure, but its prevalence:

- increases with age — to approximately **75 percent** of persons over age **75**.
- is greater in black Americans than in whites, particularly at severe levels where the rates are **three times greater** in blacks.
- is higher in men than women; however, because of the higher prevalence in women over age 65, the total number of persons with high blood pressure is very closely divided between the sexes.

Awareness and Control Data

Rates of awareness, treatment, and control among persons with high blood pressure have increased over time. By 1980, the most recent year for which national data are available, almost three-fourths of persons with high blood pressure were aware of their condition, more than one-half were taking antihypertensive medication, and more than one-third had controlled their high blood pressure.

Demographic trends show that rates of awareness, treatment, and control increase with age.

More women than men are aware and treating their high blood pressure, and almost twice as many women as men have their high blood pressure under control.

Compared to whites, black persons with high blood pressure have higher rates of awareness and similar rates for taking medication, but slightly lower rates of control.

Morbidity and Mortality

High blood pressure is the major factor underlying the 500,000 strokes and the 155,000 stroke deaths occurring annually in the United States. It is also a contributing factor in the 1,500,000 heart attacks and 567,000 heart attack deaths each year. Heart disease is the leading cause of death for American men and women of all races.

The age-adjusted stroke mortality rate has declined by nearly 50 percent from the inception of the NHBPEP in 1972 to 1985, and the mortality rate for coronary heart disease declined almost 35 percent over the same time period. Stroke is still the third leading cause of death in the United States, and stroke mortality rates for blacks are almost twice as high as those for whites.

Physician visits for hypertension increased by more than 50 percent from 1972 to 1985, while visits for all causes were up only 7 percent during the same period.

Lifestyle Factors

Obesity

Obesity has been found to be clearly related to high blood pressure, and weight reduction is recommended for all obese patients with high blood pressure. The 1985 National Health Information Survey tells us that almost one-half of all hypertensive persons have been advised by a health professional to lose weight.*

The prevalence of obesity among black women is much higher than for any other race-sex group. Black women, age 45 to 54 years, are twice as likely to be obese as are their white counterparts.

Sodium

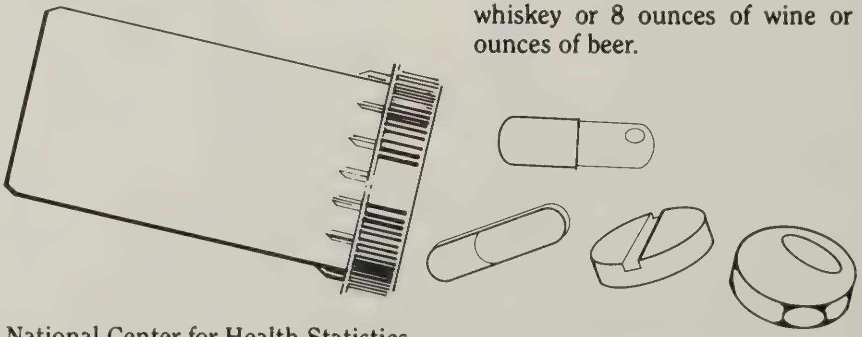
Historically, a high sodium intake has been associated with high blood pressure in some individuals. Since there is no apparent potential for harm, moderate sodium restrictions have been recommended for all persons with high blood pressure. Survey data indicate that almost three-fourths of persons with high blood pressure have been advised to cut their sodium intake and that more than 90 percent of those so advised are currently restricting dietary sodium.*

Survey data also indicate:**

- Among persons told to restrict their sodium intake by a professional, few (20 percent) were advised to use food labeling information. Only 8 percent were given specific limits to the amount of sodium they should consume daily.
- One-half of all persons using food labels to restrict sodium find the language and terminology used in the labels confusing.
- One-third of Americans who have seen low-sodium recipes have tried one, and one-half of those who are aware of low-sodium products in the grocery store have purchased one.

Alcohol

Heavy alcohol consumption has been shown to elevate blood pressure, and it is often difficult to achieve control in persons with a high intake of alcohol. Therefore, it is recommended that high blood pressure patients who drink do so in moderation, i.e., less than 2 ounces of ethanol daily. One ounce of ethanol is contained in 2 ounces of 100-proof whiskey or 8 ounces of wine or 24 ounces of beer.



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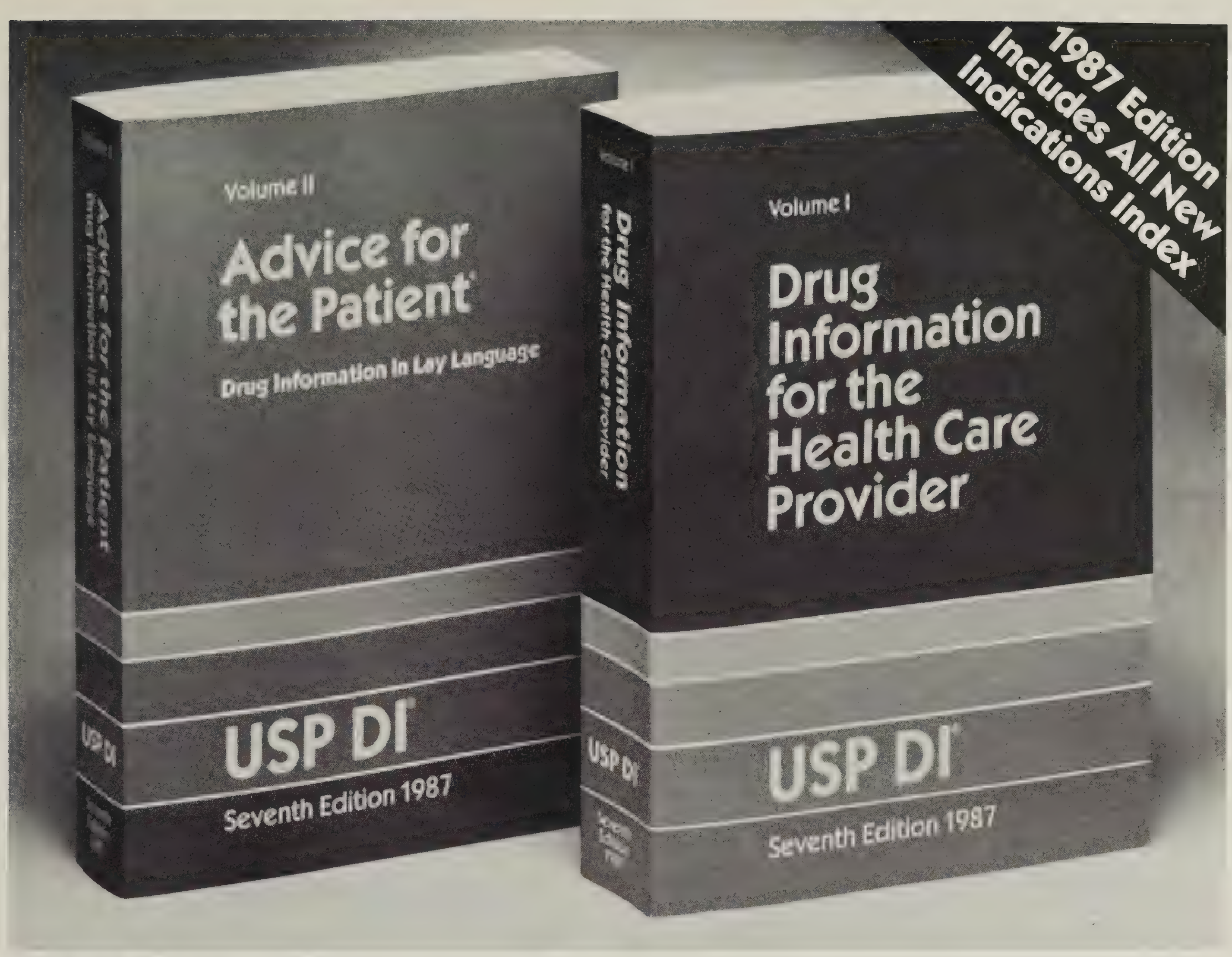
*1985 National Health Interview Survey, National Center for Health Statistics.

**1983 Consumer Food Survey, National Heart, Lung, and Blood Institute and Food and Drug Administration.



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Steroid Hormones: Wide Availability Promotes Research, Treatment of Many Diseases

Imagine a scenario in which control of your reproductive functions was dependent upon tracking down and eating certain plants. The California quail faces just such a predicament: In years with little rain, its principal food source is desert plants containing steroid hormones. These inhibit quail reproduction, limiting the population to a size the desert can feed.

The idea of humans in a similar situation is not so farfetched. We use steroid hormones—in the form of birth control pills—to control reproduction. Today, these generally come not from plants or animals, but from microbes.

Conversely, some people don't produce enough of these hormones normally and are dependent on external sources. Steroid deficiency is linked to impotence in men, infertility and early menopause in women, as well as a host of serious medical conditions.

Steroid hormones—derived from cholesterol and produced by the adrenal glands—control a wide array of biological processes in the body. It wasn't until the 1930s that humans discovered the potent hormonal and anti-inflammatory properties of steroids. This finding attracted widespread attention, and a team of researchers soon applied it to the treatment of rheumatoid arthritis. They won a Nobel Prize for that discovery.

In 1949, cortisone, an anti-inflammatory steroid hormone, was synthetically manufactured for the first time by chemists at The Upjohn Company, using a process that involved microbiological fermentation. Prior to this breakthrough, cortisone was produced by a very costly and tedious process requiring extraction of small amounts of the hormone from tons of cow adrenal glands or from exotic plants containing cortisone precursors.

The successful synthesis of cortisone made the hormone widely available and affordable for the first time to people who desperately needed it. Upjohn's technique ushered in the era of steroidal anti-inflammatory treatment.

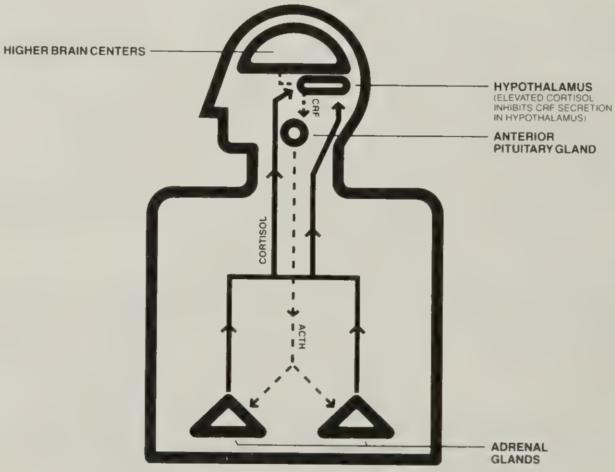
Today a variety of synthetic steroidal drugs are available for the treatment of arthritis, as well as numerous other incapacitating illnesses.

Corticosteroid Sources in Your Body

The key to appreciation of steroid hormones' diversity lies in understanding their basic biology. There are two types of natural *corticosteroids* (so named because they come from the outer layers, the cortex, of the adrenal glands), both naturally produced from cholesterol. The *mineralocorticoids* help regulate sodium and potassium levels and other body minerals. They promote proper muscle and nerve function as well as maintenance of adequate blood volume and pressure. The *glucocorticoids* regulate sugar and protein metabolism and possess potent anti-inflammatory and immunosuppressive properties.

Under ordinary conditions, the brain—specifically, the hypothalamus and the "master gland," the pituitary, (see figure #1) controls corticosteroid (cortisol) secretion. When blood levels of cortisol fall, the hypothalamus sends a chemical messenger (called a releasing factor) to the pituitary gland, signaling it to release another chemical messenger, adrenocorticotropic hormone (ACTH) into the bloodstream. ACTH stimu-

FIGURE 1 **REGULATION OF CORTISOL PRODUCTION BY THE HYPOTHALAMUS AND PITUITARY GLAND IN THE BRAIN**



Cortisol is produced by the adrenal glands located above the kidneys. When cortisol blood levels fall, the hypothalamus in the brain sends a chemical signal (CRF) to the pituitary gland. The pituitary gland stimulates the synthesis of cortisol by releasing a second chemical messenger (ACTH). The signal is turned off when the hypothalamus detects the elevated cortisol level.

ACTH = ADRENOCORTICOTROPIC HORMONE
CRF = CORTICOTROPIN RELEASING FACTOR

CRF STIMULATES ACTH RELEASE FROM PITUITARY
ACTH STIMULATES CORTISOL RELEASE IN ADRENAL GLANDS
CORTISOL INHIBITS CRF IN HYPOTHALAMUS

lates the adrenal gland to secrete cortisol. The hypothalamus monitors the blood levels of cortisol and turns off the signal to the pituitary gland once cortisol levels return to normal.

However, in adrenal insufficiency this regulatory system fails, and specific diseases develop. *Addison's disease,* characterized by weakness, weight loss, irritability, lethargy and low blood pressure, is associated with a *deficiency* of adrenal hormones. *Cushing's syndrome,* marked by hypertension, thin skin, accumulation of abdominal fat, "moon face," osteoporosis (loss of bone substance) and red cheeks, is linked to an *excess* of the production of adrenal hormones.

Steroid Hormone Mechanism of Action

"At the molecular level, corticosteroids bind to specific steroid receptor molecules found within most cells," says Susan Katz, M.D., assistant professor of medicine at Albert Einstein College of Medicine in New York City. Once bound, they alter the cell's production of proteins.

Another group of potent, hormone-like substances, the *prostaglandins,* appear to be involved in inflammatory and allergic reactions as well. Steroids inhibit the formation of certain prostaglandins by preventing the release of prostaglandin precursors.

"It's not clear, however, how cellular changes produced by steroids are related to their therapeutic effects," adds Dr. Katz. "Steroids stabilize the cell membrane and cause blood vessels to constrict. These effects probably underlie their most important clinical properties."

Many Applications for Steroid Therapy

The most widely exploited property of corticosteroids is their ability to reduce localized swelling, redness and tenderness—aspects of inflammation. However, it is important to realize that while corticosteroid therapy reduces inflammation, it may mask the underlying disease. So the underlying disease itself must be aggressively treated at the same time that steroids are administered.

Corticosteroids are also used therapeutically for their immunosuppressive properties. They reduce the individual's defense against infection. Taking advantage of this, physicians use steroids to suppress immunity in *organ transplant* patients to prevent rejection of the transplanted organs.

Another use for steroids is in the treatment of *autoimmune disorders,* such as rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis and myasthenia gravis. In these diseases, the body's immune system fails to distinguish infecting foreign invaders from its own components. And the body mistakenly produces antibodies against itself. Steroids effectively suppress this destructive cycle.

Steroids are also used to treat inflammation of the eye and skin, hormone-dependent tumors of the breast, leukemia, lymphoma and respiratory disorders.

TABLE 1. **THE MANY USES OF STEROID HORMONES**

I	**Cancerous Diseases**	Leukemia Lymphoma Breast Cancer (estrogen-dependent)
II	**Central Nervous System Disorders**	Mild/Moderate Spinal or Head Injury Localized Brain Tumor
III	**Hormonal Disorders**	Adrenal Gland Insufficiency (Addison's Disease) Hormone Replacement (menopause, physical development, impotence)
IV	**Respiratory Disorders**	Asthma Aspiration Pneumonitis
V	**Arthritic Disorders**	Rheumatoid Arthritis Osteoarthritis Bursitis
VI	**Allergic States**	Severe Bronchial Asthma Serum Sickness Drug Hypersensitivity Reaction Transfusion Reaction Nonresponsive Allergic Rhinitis and Hay Fever
VII	**Eye Disease**	Inflammation of the Eye Allergic Conjunctivitis
VIII	**Skin Diseases**	Psoriasis Eczema Contact Dermatitis Exfoliative Dermatitis

A Word About Steroid Toxicity

There is good reason to use steroids cautiously, reserving them only for conditions that do not respond to more moderate treatment. The prolonged use of oral or injected steroids can result in suppression of adrenal function, along with increased susceptibility to infection, weakness, osteoporosis and behavioral changes.

Abrupt withdrawal of long-term steroid therapy may activate the condition for which steroids were initiated. Antibiotic therapy is often necessary to combat bacterial or fungal infection in patients treated with immunosuppressive steroids.

In general, steroids should be administered in what is determined to be the smallest effective dose in an attempt to avoid these complications. Treatment is usually tapered off gradually as the crisis abates.

Pulse-dosing—intermittent high doses of steroids over short periods of time—may be more effective in treating certain diseases than long-term treatment with low doses. In the future, novel drug delivery systems that target drugs directly to the problem area will help to reduce toxicity and improve effectiveness.

Sex Hormones Are Also Steroids

The female ovaries and the male testes are responsible for the production of another group of steroids, the sex hormones—estrogen, progesterone and testosterone. These hormones are responsible for sexual development at puberty and play an important role throughout our lives in shaping body and behavior.

The normal menstrual cycle in women is governed by the cyclical production of estrogen and progesterone. These hormones are some of the most frequently prescribed drugs in the world today. As many as 50 million women worldwide are taking some form of oral contraception to inhibit ovulation. Combined preparations of estrogen and a progesterone-type agent (progestin) are nearly 100 percent effective in preventing pregnancy. The "mini pill," containing only the latter, is about 98 percent effective but avoids many of the side effects related to estrogen.

In menopause, the ovaries gradually stop producing hormones and menstruation ceases. Replacement therapy with a combination of estrogen and a progestin often provides relief from hot flashes, vaginal thinning and osteoporosis.

Replacement therapy with androgen (testosterone; Depo-Testadiol, Upjohn) is used primarily to promote genital development and normal growth in the deficient male. Testosterone is an effective treatment for some types of impotence as well.

Anabolic Steroids: How Dangerous Is Their Use?

Androgens are also used by athletes who exploit these drugs for their anabolic (body-building) properties. The androgens can cause dramatic weight gain in short periods by reducing the body's ability to utilize protein.

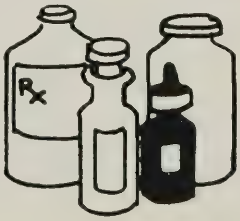
It is believed that some athletes self-administer high doses of a mixture of oral and injectable steroids during training and taper them off prior to competition to avoid detection.

In the few controlled studies addressing this issue, anabolic steroids increased body weight (apparently through water retention), but no clear effect on muscle mass could be documented.

Prolonged anabolic steroid use may result in acquired masculinization in females, feminization in males, insomnia, irritability and a variety of serious blood disorders.

A Handful of Steroids Provide an Abundance of Treatments

Steroid therapy has constituted a major advance in clinical medicine in the past 35 years. Armed with only a few of the many steroids available, the physician can now bring about remission of many chronic diseases and reduce suffering that would otherwise be intractable.



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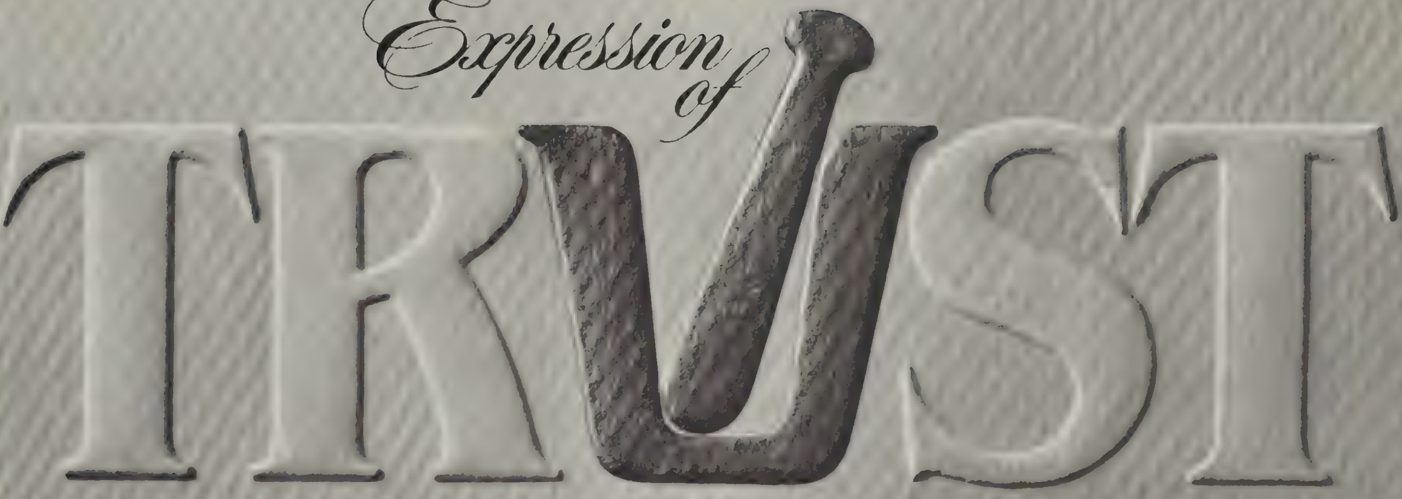

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- **WATCH YOUR PACKAGES SHIPPED GROW**–The "average" center ships over 2,500 packages in the first year. The average growth of packages shipped in the second year is over 15%.
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- **OPTIONAL SERVICES**–Many retailers are offering packaging, taping, and strapping services to build profits.
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- **YOU CAN BE AS SUCCESSFUL AS OTHER RETAILERS**–Careful record keeping by Kings Drug in Hickory, N.C. indicate a net profit of more than $5,000 from their Package Express Center® in 1985.
- **HIGH RETURN PER SQ. FT. OF FLOOR SPACE** It's easy to make a decision to add this service to your store. Thomas Drug in Huntsville, AL shipped 9,000+ packages and had a net profit of more than $10,000 in 1985. Retailers are reporting sales per sq. ft. from a low of $140 to over $500!
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- **CONVENIENCE**–No standing in line at post offices; no hunting UPS sub-stations with limited hours; no waiting 24 hours for residence pickup; no unnecessary trips.
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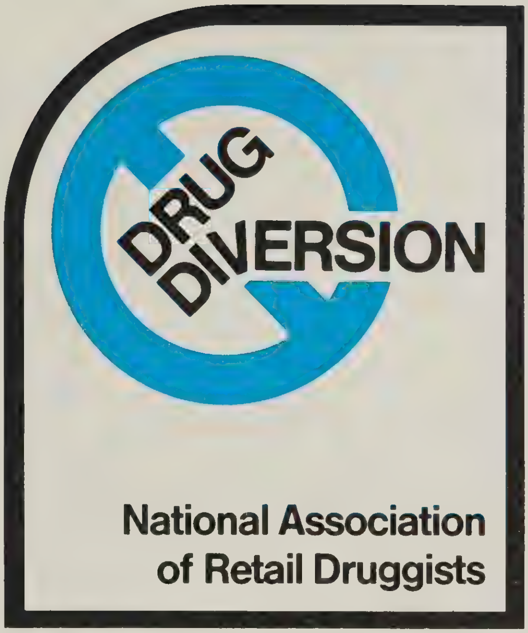
The Baltimore Metropolitan Pharmaceutical Association held its annual Banquet on March 8th. BMPA President Howard Schiff (left) presents the Past President's Award to George C. Voxakis (right).



The NARD has adopted this logo in support of the Federal Drug Diversion Legislation, HR 1207, currently being considered by Congress.

Toastmaster and BMPA President-Elect Paul Zucker (left) presents Sylvia Voxakis with a special Pharmacist's Mate Award. The Banquet was held at Blue Crest North in Baltimore.

Pharmacist-Legislator Delegate Donald Elliott (right) shown with his wife and Pharmacist Jeannie Elliott, was the featured speaker at the BMPA Banquet.

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The Compounders Corner

by
Loyd V. Allen, Jr., Ph.D., and M. Lou Stiles, M.S.
The University of Oklahoma College of Pharmacy
Oklahoma City, Oklahoma 73190

PRESSURE INDICATING PASTE:

Rx	Zinc Oxide Ointment	529.28 G.
	White Petrolatum	171.13 G.
	Mineral Oil	249.66 G.
	White Wax	49.93 G.
	Flavoring	q.s.

PREPARATION:

Reduce White Wax to a fine state of subdivision by grating. Then heat the grated wax until it melts using a double boiler to eliminate the possibility of scorching. Heat the Mineral Oil and White Petrolatum in a separate double boiler to a temperature near that of the wax. Add the Mineral Oil/White Petrolatum mixture *very* slowly in small increments and with continuous stirring to the melted wax. After thorough mixing of the two oleagineous liquids, the Zinc Oxide Ointment, which has been divided into small increments, is slowly added with constant stirring. When the mixture appears to be completely melted, displaying a uniform creamy white appearance, the heat is removed and the mixture is allowed to cool. If a volatile flavoring agent is used, it would be added during cooling just before solidification occurs. The "paste" can be poured while still slightly warm into the desired size ointment jars, or it may be allowed to solidify and then lifted into the appropriate containers via a spatula.

USE:

An indicator of pressure points in prosthodontics.

PACKAGING:

Air-tight, wide-mouth plastic or glass jars.

LABELING:

Keep tightly closed; for external use only. Keep away from heat.

STABILITY:

This preparation is stable for several months providing proper storage and packaging are maintained. Containers should remain tightly closed when not in use and be stored at room temperature.

DISCUSSION:

Pressure Indicating Paste, synonym P.I.P. Paste, or P.I.P. Prep, is applied in an evenly distributed thin layer to the inside area of oral dentures, which are then in turn inserted into the patient's mouth. The patient is then instructed to "bite down" on the plate. Upon removal from the patient's mouth the prosthodontist can then identify the pressure points by "reading" the indentations made in the P.I.P. Paste layer. Most prosthodontists prefer a firm or viscous preparation. It is therefore crucial in maintaining the integrity of the product to avoid storing at elevated temperatures. At higher temperatures the product tends to become a "soupy" semi-solid, exhibiting diminished readability.

Zinc Oxide Ointment is available commercially. It can also be compounded by combining 200 grams of Zinc Oxide with 150 grams of Mineral Oil to form a smooth paste, which in turn is mixed into 650 grams of white ointment to provide 1000 grams of Zinc Oxide Ointment. White Ointment is a 5% White Wax in White Petrolatum preparation.

Zinc Oxide is proported to exhibit mild antiseptic and astringent activity. It has long been used in dentistry as an ingredient in dental cements as well as a temporary filling.

White Ointment is pharmaceutically classified as an emollient. It quite often is used as a vehicle for ointments or dermatological preparations, as is the White Petrolatum component of this formulation.

White Wax (White Beeswax) is employed, in this preparation and others, as a stiffening agent. The wax constitutes the most difficult problem encountered in preparing P.I.P. Paste because the liquid form of it will instantaneously solidify when it is combined with cooler substances, thus causing the wax to form lumps.

Commonly used flavoring agents in this formulation have been Lemon Oil and Peppermint Oil, both of which have had good patient acceptance.

SOURCE OF INGREDIENTS:

All of the ingredients included in this formulation are readily available through local drug wholesalers.

Classified Ads

Classified ads are a complimentary service for members.

Free employment placement service available from the MPhA—Call Beverly at (301) 727-0746.

Hotline for Pharmacists Rehabilitation Committee

(301) 727-0746

FDA Hotline for AIDS 800-342-AIDS

Hotline for impaired Physicians (301) 727-0120

Hotline for impaired Dentists (301) 964-2275

The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

PHARMACIST WILL FILL IN FOR VACATION, SICKNESS, TIME OFF, FOR INDEPENDENT PHARMACY, IN ROCKVILLE, POTAMAC AREA CALL AFTER 6:00 p.m. 301-424-7171

Tablet Counter for sale call Glenn 282-3300

CASH IN RETURNS is a new return goods service for Maryland pharmacists. The comprehensive system is run by Phil Karn, Sr., P.D.

Invoices, packing slips, shipping labels, and postcards requesting return authorization are all supplied with little effort on the part of the pharmacy.

A limited number of free demos to introduce the service and to finish beta testing available. Call evenings at (301) 252-1504.

Menopause Publication is Available

Contrary to stereotypes about menopause, researchers find that most women have no regrets about reaching this stage in life. Menopause is a natural process that takes place smoothly for most women and is accompanied by only mild (or even no) symptoms. For the few women with severe symptoms, treatments are available today to help relieve discomfort. Overall, during menopause women tend to be as healthy as they were before menopause and no more prone to illness.

The National Institute on Aging (NIA) has updated *The Menopause Time of Life* to answer common questions asked about menopause. This phamphlet includes descriptions of physical changes that occur during menopause and characteristic symptoms. Related topics cover treatment for menopause symptoms, use of estrogen, osteoporosis, nutrition, physical fitness, sexuality, and surgical procedures (hysterectomy and oophorectomy). *The Menopause Time of Life* is intended for women of all ages and may be helpful to family members, health care providers, and the press.

To obtain your free copy, write to the NIA Information Center/Meno, 2209 Distribution Circle, Silver Spring, MD 20910; or call 301/495-3455.

Multiple copies of the booklet can be purchased from the Government Printing Office for $1.00 each. (Bulk orders of 100 or more will receive a 25 percent discount.) Please indicate stock number 017046-00056-0 on your order, and send a check or money order (Visa and Master Charge are also accepted) to Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

calendar

May 12 (Thurs)—Alumni Association Annual Meeting and Election
May 17 (Sun)—CECC—Arthritis Seminar—Marriott Inner Harbor
May 21 (Thurs)—Alumni Association Annual Graduation Banquet
June 21–25—MPhA ANNUAL CONVENTION—OCEAN CITY, Maryland
Oct. 9–11—MSHP Annual Seminar, Williamsburg VA
Oct. 18–23—NARD Convention
Oct. 23–25—Post NARD Convention side Trip to San Francisco
Jan. 17–24, '88—MPhA Trip to Curacao in the Caribbean

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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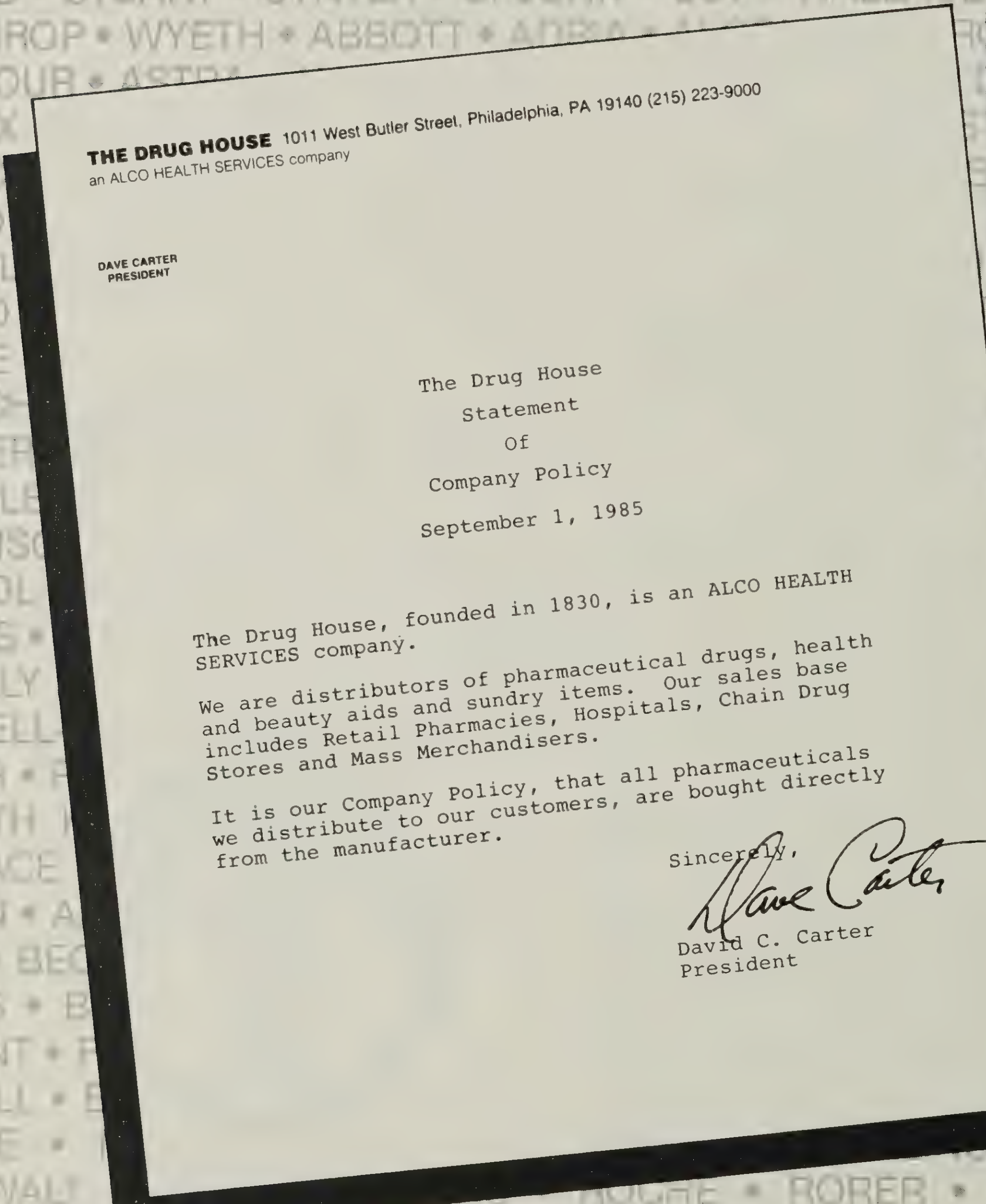

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We are distributors of pharmaceutical drugs, health and beauty aids and sundry items. Our sales base includes Retail Pharmacies, Hospitals, Chain Drug Stores and Mass Merchandisers.

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Sincerely,

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THE
MARYLAND
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Official Journal of
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Association

June, 1987
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NO. 6

OTC Antacid Therapy—An Update

—J. Richard Wuest
—Thomas A. Gossel

Licensing Boards and Impaired Professionals

—Roslyn Scheer
—Donna Dorsey

Clues to Impairment in Pharmacists

The Pharmacist and Hospice—New Column

—Diane White
—Lynda Oderda
—Ilene Zuckerman

Employer Power—Commentary

—Jim Dickinson

Determining Perceptions of Over-The-Counter Medication Use in the Elderly

—Judy McKay
—Thomas LaMartina
—Alan McKay

Compounders Corner—Carafate Suspension

—Loyd Allen, Jr.
—M. Lou Stiles

THE MARYLAND PHARMACIST

650 WEST LOMBARD STREET
BALTIMORE MARYLAND 21201
TELEPHONE 301/727-0746

JUNE, 1987 VOL. 63 NO. 6

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LOOKING BACK. . . .

Over the past months, we've talked of many things . . .

An analogy was presented that air traffic controllers and pharmacists had much in common—potentially life threatening situations, the stress, the burnout. Some of you agreed. We spoke of the importance of unity. "Let both sides explore what problems unite us instead of belaboring those problems which divide us." We spoke of dreams.

I asked once, "Does Anyone Read this Page?" Apparently, someone did—and told me what he thought. I brought to your attention that "Benedict Arnold Was a Pharmacist!" and warned us not to follow suit. And, happily, I announced "The Thrill of Victory"—reporting a major victory for the pharmacy community.

If, at times, I've seemed too negative, I'm afriad it's because conditions in our profession have been negative. Times have changed; they've become more difficult. One of my children recently came across and pointed out to me a description by the poet Vergil of an ancient practitioner of our profession.

> "He preferred to know the power of herbs and their value for curing purposes, and, heedless of glory, to exercise that quiet art."

It ain't the same anymore!

As my term as president comes to a close, I'd like to be able to say something very profound—that will stay with you always. Instead, I'll leave you with someone else's words:

> "And must we part? Well—if we must, we must—and in that case, the less said the better."

Thanks,

George C. Voxakis, P.D.

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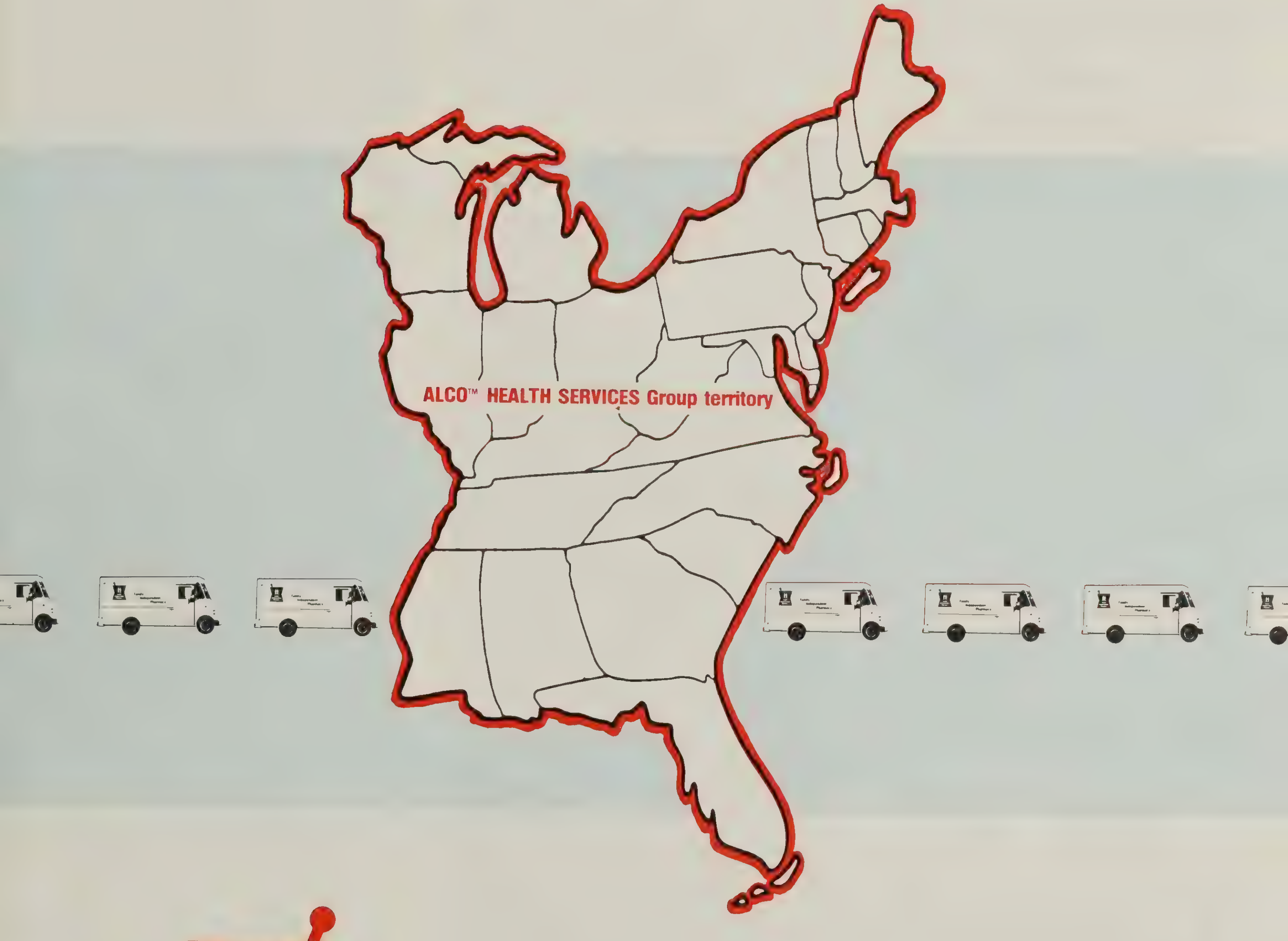

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STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. IV, NO. 5

OTC Antacid Therapy — An Update

by **J. Richard Wuest, R.Ph., Pharm.D.**
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. discuss contemporary uses for OTC antacids, and illustrate important differences between them; and
2. summarize labeling requirements for antacids, including product uses, warnings and precautions, and drug interactions.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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Objectives

At the conclusion of this lesson, participants will be able to:

1. list the most commonly used antacid ingredients, and explain their pharmacologic action;
2. distinguish between the terms systemic and nonsystemic antacids, and discuss why this nomenclature is not truly accurate;
3. describe the warning statements that must accompany antacid products, and provide the basis for each warning;
4. state the major drug interactions associated with antacid therapy and comment on the clinical significance of each;
5. list the two categories of OTC ingredients that may be combined with antacids and marketed as OTC antacid combinaton products; and
6. review important consumer information regarding antacid therapy.

It is estimated that close to one billion dollars is spent on OTC antacids each year. Antacids also head the list of OTC products for which consumers ask pharmacists for advice before purchase.

Until the introduction of the histamine$_2$ (H_2) antagonists (e.g., Tagamet®, Zantac®) in the late 1970's, antacids were the mainstay of therapy for peptic ulcer disease (PUD). Antacids are effective in preventing pain of PUD. However, due to better patient acceptance and compliance, the H_2 antagonists have largely replaced them as agents of choice for treating PUD.

However, antacids are still used for patients in whom H_2 antagonists are not indicated, such as during pregnancy or nursing, in children under 16, and in patients sensitive or intolerant to them. It is also rational to use antacids concurrently with H_2 antagonists. Even in low dosages, antacids provide almost immediate relief of PUD symptoms.

A commonly misunderstood concept is that antacids "neutralize" gastric acid. It is neither possible nor necessary to completely neutralize gastric acid. Raising the pH to 4 will prevent conversion of pepsinogen (pepsin's precursor) to pepsin.

The proteolytic enzyme *pepsin* is the troublemaker in PUD. It digests gastric tissue leading to erosion. Antacids encourage granulation tissue (scab) formation over the ulcer crater to protect underlying tissue while the body heals itself.

Prevention of gastrointestinal (G.I.) pain can usually be obtained with doses taken two to three hours after each meal and "prn" doses in between. Acid production is high after meals, but food has sufficient buffering capacity. As the stomach empties, acidity peaks one and one-half to two hours later, and remains high for another one to two hours.

A major problem with using antacids to treat PUD is noncompliance. This is related to their unpleasant taste and necessity for frequent dosing. A recent innovation was the development of a gum-like chewable dosage form (e.g., Tempo, Remagel). Their manufacturers claim significantly improved patient acceptance and compliance.

Antacids remain agents of choice for self-medicating mild, uncomplicated upper G.I. distress, which is related to excessive acid production. Manufacturers of OTC antacids can advertise their products for acid indigestion, sour stomach, heartburn, and upset stomach associated with any of the other three symptoms. Representative OTC antacid products are listed in Tables 1 and 2.

OTC Antacid Ingredients

Chemical antacids that are safe and effective for self-medication include salts of aluminum, bismuth,

TABLE 1

OTC Single Entity Antacid Products

Trade Name	Ingredient
Alagel	Aluminum hydroxide
Alternagel	Aluminum hydroxide
Alu-Cap/Alu-Tab	Aluminum hydroxide
Amitone	Calcium carbonate
Amphogel	Aluminum hydroxide
Basaljel	Aluminum carbonate
Bell/ans	Sodium bicarbonate
Chooz	Calcium carbonate
Dialume	Aluminum hydroxide
Dicarbosil	Calcium carbonate
Lowsium	Magaldrate (hydroxymagnesium aluminate)
Milk of Magnesia	Magnesium hydroxide
Phosphaljel	Aluminum phosphate
Riopan	Magaldrate (hydroxymagnesium aluminate)
Rolaids	Dihydroxyaluminum sodium carbonate
Soda Mint	Sodium bicarbonate
Tums	Calcium carbonate

calcium, magnesium, potassium, and sodium. Anions commonly combined with them are bicarbonate, carbonate, citrate, hydroxide, and phosphate. The FDA/OTC advisory panel that reviewed antacids placed limits on the total daily doses of a few salts that can be marketed in OTC antacids. They are listed in Table 3.

Products containing sodium salts have traditionally been referred to as *systemic* (absorbable) antacids because they readily ionize, and are soluble and appreciably absorbed. Aluminum, calcium and magnesium salts have been called *nonsystemic* (nonabsorbable) antacids because of their limited absorption.

This classification is not truly accurate because it implies that the latter salts are not absorbed. In the warm gastric environment of pH 1 to 3, they do partially dissolve and ionize. This occurs to a small degree, but systemic effects can occur, especially if the patient has compromised renal function.

Specific Salts

Sodium bicarbonate is the fastest-acting and most potent of all antacid agents. It is excellent for periodic, short-term, rapid relief of minor heartburn, sour stomach, acid indigestion or upset stomach.

However, sodium bicarbonate does not provide the prolonged relief needed for PUD therapy. It can also lead to acid rebound, i.e., increased acid production due to raising the pH above 4. At higher pH, the body attempts to compensate by increasing acid secretion. This further aggravates the ulcer condition.

On reaction with gastric acid, sodium bicarbonate releases carbon dioxide. Even though it is unlikely, this may distend the gastric wall leading to possible perforation. Effervescent products further complicate the problem and should not be used regularly for relief of any G.I. symptom. Additionally, they are actually contraindicated in chronic PUD therapy.

Another problem with long-term use is that absorbed bicarbonate may promote alkalosis in patients with impaired renal function. In addition, patients on a low sodium diet may exceed their daily allotment with the 1-to 2-gram doses that some products require.

Calcium carbonate was once considered the best antacid. It is rapid acting, potent, and exerts a relatively prolonged action. It causes fewer systemic effects than sodium bicarbonate, and is a more efficient neutralizer of acid than aluminum or magnesium salts.

TABLE 2

OTC Combination Antacid Products

Trade Name	Ingredients*				
	Al	CA	MG	SIM	Other
Alkets		1	2,3		
Aludrox	4		2		
A-M-T	4		5		
Bisodol		1	2		
Camalox	4	1	2		
Creamalin	4		2		
Delcid	4		2,3		
Di-Gel	4		2	6	
Gaviscon	4		5		7
Gelusil	4		2	6	
Kolantyl	4		2		
Kudrox	4		2		
Lo-Sal		1	2		
Maalox	4		2		
Maalox Plus	4		2	6	
Mylanta	4		2	6	
Ratio		1	3		
Remagel	4		2		
Riopan Plus			8	6	
Rulox	4		2		
Silain-Gel	4		2	6	
Simeco	4		2	6	
Tempo	4	1	2	6	
Titralac	1				9
WinGel	4		2		

*1 = calcium carbonate
2 = magnesium hydroxide
3 = magnesium carbonate
4 = aluminum hydroxide
5 = magnesium trisilicate
6 = simethicone
7 = sodium bicarbonate
8 = magaldrate (see Table 1)
9 = glycine

TABLE 3

Upper Daily Limits for Antacids

Aluminum salts: 8 gm/day
Bicarbonate: 200 mEq/day in persons under 60; 100 mEq/day in persons over 60
Calcium: 160 mEq/day
Citrate: 8 gm/day
Di- or monocalcium phosphate: 2 gm/day
Tricalcium phosphate: 24 gm/day

However, it also causes acid rebound. Calcium directly stimulates gastric mucosa to cause reflex hypersecretion of acid. There is normally sufficient antacid present to combat excess acid, but some patients may experience problems. Some of the ionized calcium is absorbed and hypercalcemia may result. This is not of major significance in most persons.

Another potential problem involves patients with a tendency to form carbonate renal stones. Addition of both calcium and carbonate ions increases their propensity for precipitation in the renal tubules. Nonetheless, the majority of persons who use calcium carbonate suffer no ill effects.

Constipation is the most commonly reported side effect, and is reversible on discontinuance of therapy. Therefore, calcium carbonate is safe for periodic use, for self-treating symptoms of acid indigestion, heartburn, sour stomach and upset stomach.

Magnesium salts are popular OTC antacids. Their effectiveness lies between salts of calcium and aluminum. Soluble magnesium salts are also saline cathartics. This leads to their most common side effect, increased bowel movements. In fact, while lower doses of magnesium hydroxide (e.g., milk of magnesia) are effective antacids, larger doses work well as cathartics.

Magnesium ions may be absorbed. This is of little consequence in a normal, healthy adult because magnesium is readily excreted from the kidney. Patients with impaired renal function may have difficulty doing so, and may, therefore, accumulate excessive amounts in the blood. Hypermagnesemia can induce hypotension, nausea and vomiting, and depressed muscle reflexes. Magnesium is also a strong CNS depressant. Toxic levels cause severe depression, coma, and death.

Aluminum salts include aminoacetate, carbonate, hydroxide, and phosphate. Aluminum hydroxide is the most commonly used of the four.

Aluminum salts are the least potent of all antacids in terms of neutralizing capacity. Aluminum also has astringent and adsorbent actions in the G.I. tract, and can cause constipation. It is best used in combination with magnesium salts. The cathartic action of magnesium balances the constipative effect of aluminum. When a single entity aluminum salt antacid is requested, the individual should be advised to drink lots of fluids throughout the day to minimize constipative effects.

For years it was believed that systemic side effects from aluminum were rare since little was absorbed. In the late 1970's, evidence began to mount that chronic toxicity can occur in brain tissue, bone and parathyroid glands in patients with renal disease. Retrospective studies suggest that consumption of aluminum-containing antacids may have adverse effects on metabolism of phosphorus, calcium and fluoride, and induce skeletal abnormalities. No direct correlation has been proven, but it is known that patients with Alzheimer's disease have elevated levels of aluminum in their brain tissues.

Labeling Requirements

Antacids are nontoxic in most individuals. But some persons, because of one or more underlying disorders such as renal disease or hypertension, may be exposed to adverse effects when these products are misused.

The following warning must appear on all OTC antacids: "Do not take more than (the dose) in a 24-hour period, or use (the product) more than two weeks except under the advice and supervision of a physician." This warning is necessary because persons experiencing G.I. distress over a prolonged period may actually have an underlying serious pathological condition requiring physician intervention.

Potassium-Containing Antacids. Potassium is one of the approved antacid cations, although it is not commonly used. In the normal healthy individual with adequate renal function, there is no medical problem with potassium. The kidney excretes excess potassium that the body does not need. In persons with kidney disease, however, potassium may accumulate to cause life-threatening toxicity.

Products containing more than 25 mEq of potassium per daily dose must be labeled: "Do not use this product except under the advice or supervision of a physician if you have kidney disease."

Magnesium-Containing Antacids. The same warning statement is required on labels of products containing more than 50 mEq of magnesium per daily dose. While magnesium-containing products are not contraindicated in all patients with kidney disease, these patients should use them only under the supervision of a physician.

Sodium-Containing Antacids. Products containing more than 5 mEq of sodium per daily dose must bear the warning: "Do not use this product except under the advice and supervision of a physician if you are on a sodium-restricted diet." Patients with sodium-restricted diets generally have heart disease or hypertension. Excessive sodium can be retained by the body, increasing body fluid. The resulting edema can aggravate the above mentioned conditions.

Items such as Alka-Seltzer and Bromo Seltzer may contain more than 1 gm of sodium bicarbonate per dose (approximately 12 mEq of sodium), and should be avoided by these patients. Table 4 lists the quantity of sodium in representative OTC antacids. Most nonabsorbable antacids contain considerably less sodium than the amount constituting the need for the warning. If the warning is not listed on the label, the product is safe for use by persons on sodium-restricted diets.

Although not a warning in the same sense as those previously listed, the labeling of antacid products must advise consumers of the possibility of a laxative or constipative effect. Products which have been shown to cause laxation in more than 5 percent of the target population must bear the warning: "May have a laxative effect." Those causing constipation in greater than 5 percent of the target population must state: "May cause constipation."

Drug Interactions

Tetracycline. Studies have shown that tetracycline absorption may be altered by antacids as a result of two different phenomena. First, tetracycline derivatives chelate with divalent and trivalent cations which result in reduced absorption. Second, a rise in gastric pH alone will reduce tetracycline absorption. This increased gastric pH also augments the chelation process.

The problem is easily overcome by taking the tetracycline product one to two hours before the dose of antacid. This separation of doses reduces

TABLE 4

Sodium Content of Selected Antacid Products

Product	Mg Sodium Per Tablet	Mg Sodium Per Teaspoon or Dose
Alka-Seltzer	296	—
Alterna Gel	—	2.0
Aludrox	1.6	1.2
Amphogel 5 gr	7.0	7.0
Bell/ans	144	—
BiSoDol Powder	—	157
Bromo Seltzer	—	761
Camalox	1.5	2.5
Creamalin	41.0	—
Delcid	—	15
Dicarbosil	2.3	—
Di-Gel	5.0	8.5
ENO	—	812
Gaviscon	1.9	12.9
Gelusil	0.8	0.7
Gaviscon-2	26.8	—
Gelusil M	1.3	1.2
Gelusil II	2.1	1.3
Lo-Sal Plus	0.1	0.1
Maalox	—	1.4
Maalox #1	0.8	—
Maalox #2	1.8	—
Maalox Plus	1.0	1.1
Maalox Therapeutic	—	0.8
Mylanta	0.8	0.7
Mylanta II	1.3	1.1
Riopan	0.1	0.1
Riopan Plus	0.1	0.1
Rolaids	53.0	—
Silain Gel	2.5	4.8
Soda Mint	330	—
Tempo	2.3	—
Tums	2.3	—

the likelihood of an interaction to the point of insignificance. Since a goal of therapy is to maximize the chance for successful treatment, the best advice to give a patient taking tetracycline is to avoid antacids or dairy products (contain calcium) for at least one hour before or after a dose of tetracycline.

If the physician has specifically directed that tetracycline be taken with food or milk, the prescribed regimen should be followed. There is no strict contraindication.

Iron. Absorption of iron from supplements may be lessened by concurrent antacid ingestion. Conclusive evidence of the true significance of this interaction is lacking, and no label warning is required at this time. It is still recommended by some experts that doses of antacids and iron preparations be spaced as far apart as possible.

Other Drugs. Spacing doses of antacids and weakly acidic drugs, such as sulfonamides, nitrofurantoin, and nalidixic acid, has also been recommended because antacids may decrease their absorption. There have been no definitive studies to prove whether this is a significant interaction.

A potentially significant, but rather involved interaction may occur between antacids and sodium polystyrene sulfonate (e.g., SPS, Kayexalate). This agent is a cationic binding resin and will bind with calcium or magnesium in antacids. Although the exact mechanism of the interaction is not known, the net result is increased blood levels of bicarbonate. A serious problem could occur in patients with a tendency toward alkalosis. It is recommended that SPS be administered rectally rather than orally to patients taking antacids. This will permit it to bind with and increase the excretion of potassium without affecting antacid activity or systemic pH levels.

Antacid Combinations

There are two antacid combination groups that are considered to be safe and effective for OTC marketing. These are antacids plus an analgesic, and antacids plus an antiflatulent.

OTC **antacid-analgesic** combinations must be indicated for acid indigestion, heartburn, sour stomach or upset stomach that is accompanied by pain or headache. Also, products must be marketed in a form that consumers ingest as a solution. They can be effervescent tablets or powders that are dissolved prior to drinking. But they cannot be solid tablets or capsules that must be swallowed whole.

The combination analgesic-antacid products which the above regulations pertain to are those that contain therapeutic doses of each ingredient. Analgesic products which contain an antacid in subtherapeutic amounts for buffering effects (e.g., Ascriptin, Bufferin) are not so regulated. These are analgesic agents which are considered to be safe and effective as long as they are labeled according to regulations for OTC analgesics.

The second safe and effective combination is the **antacid-antiflatulent** group. These products must be indicated for gas associated with acid indigestion, heartburn, sour stomach or upset stomach. The only approved antiflatulent at this time is simethicone. Simethicone lowers the surface tension of gas bubbles in the G.I. tract, allowing them to coalesce, become larger, and escape into the atmosphere.

Advising Consumers

Several factors should be recalled when advising a consumer on the selection of an antacid. Liquid, chewable, and powder dosage forms are more effective than oral tablets because of their more rapid dispersion in the stomach, and their greater surface area. Since insoluble antacids rely on their large surface area for activity, it stands to reason that the smaller the particle size, the larger the surface area. Therefore, the more contact there is with the acid, the faster the action, and the more efficient it is as an antacid.

Tablets must be thoroughly chewed or sucked before swallowing. Even then, it is impossible to grind a tablet down in one's mouth to a particle size approaching that of a manufactured suspension. Additionally, tablet particles cannot be wetted sufficiently by saliva to provide as prompt an action as liquids. Thus, for open-ended requests, liquids are considered better.

The goal of therapy is not to relieve pain, but to prevent pain from occurring. When G.I. pain does occur, it means that granulation tissue is digested by pepsin, and healing is prevented.

After considering the limitations stated earlier, patient compliance is paramount. Compliance will be maximized if the product tastes good, is free of bothersome side effects, and the dosage regimen is convenient. Since the first two factors are functions of the patient's opinion, he should choose a product formulated to suit his own taste preference.

When counseling consumers who request an antacid to relieve symptoms associated with minor, short-term G.I. distress, the faster acting substances such as sodium bicarbonate or calcium carbonate can be considered. However, if any of these symptoms persist longer than a day or two, or continually recur, they may be warning signs of a more morbid condition such as PUD, chronic gastritis, gallstones, or hiatal hernia. In these instances, the person should seek professional diagnosis and assistance. All persons with G.I. distress should be advised to modify eating and drinking habits, and readjust their psychological status to alleviate anxiety or stress.

More on the "Future"

Ambulatory care center dispensing. A survey last year of 87 companies operating 540 ambulatory care centers (ACCs) showed that 47.3% of the companies dispense prescription drugs in 41.7% of the centers. By next year, 67% of the companies expect to be dispensing in one or more of their ACCs. Of those ACCs which dispense, more than 80% began dispensing within the past three years. Only 6.5% employ full-time pharmacists, and 8.5% employ part-time pharmacists. The survey was conducted by the National Association for Ambulatory Care (NAFAC).

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Licensing Boards and Impaired Professionals

ROSLYN SCHEER MAS and DONNA M. DORSEY RN

As a result of increasing experience with substance abuse and in response to changing attitudes and theories, licensing boards have begun to modify their methods of disciplining the impaired professional. Today, boards try to balance public protection with individual rehabilitation. The Maryland Board of Examiners of Nurses and the Maryland Board of Pharmacy have created procedures they believe are effective in maintaining this balance.

The responsibility of health occupation licensing boards is to protect the public from unsafe practitioners. The increase of substance abuse in our society is reflected in the health professions causing licensing boards to place greater emphasis on their role with the impaired professional. Substance abuse is one activity that places everyone at risk. The individual who is actively using drugs and/or alcohol is not safe and should not be permitted to practice. A practitioner who is a danger to patients must be removed from the practice setting until it is determined that individual can practice safely.

During the past five years licensing boards have found it necessary to reexamine their role in disciplining the impaired professional. Traditionally, the license of the impaired professional was revoked because most licensing boards believed that the individual would never recover sufficiently to permit safe practice. Experience has demonstrated that this position is not valid. The person committed to an appropriate treatment program can practice safety in a controlled setting. Confronted with this knowledge and an increased number of individuals being reported for substance abuse, boards are struggling with the dilemma of protecting the public, while supporting the rehabilitation efforts of the impaired professional.

The disciplinary process is initiated when a complaint is received by the Board concerning an impaired professional. The statutes of the Pharmacy and Nursing Boards provide civil immunity to an individual who makes a complaint, in good faith, to the Board concerning a licensee.

Currently the Board of Nursing receives the majority of these complaints from employers. Typically, the nurse is discovered falsifying records to obtain drugs for personal use. In a small number of cases, the nurse is observed consuming drugs while on duty or arrives at work under the influence of drugs and/or alcohol. Occasionally, complaints are received from peers or patients who believe the nurse is impaired. In addition, other boards of nursing disseminate reports that initiate disciplinary action by the Maryland Board.

Complaints against impaired pharmacists are generated primarily by conflict with the criminal justice system, inspection by the Division of Drug Control, or by the action of a licensing board in another state. Complaints rarely are received from patients, employers, or peers. A friend or employer is more likely to contact the Rehabilitation Committee of the Maryland Pharmaceutical Association for help than to report someone to the Board. Like the Board of Nursing, the Pharmacy Board's action often is supported by information obtained from records created and maintained by the licensee.

Investigation

Investigation of the allegation is the next step in the process. Once the investigation is completed and the Board has determined there is sufficient evidence to charge the licensee with a violation of the law, a charge letter is issued. In accordance with state law, the Board may deny a license to an applicant, reprimand a licensee, place a licensee on probation, or suspend or revoke a license. In addition, the Board of Pharmacy may impose a civil penalty not exceeding $5,000. The sanction a board chooses is based on the individual situation. The charge letter offers the licensee an opportunity to negotiate a settlement in the case at a prehearing conference prior to the full evidentiary hearing. Settlement precludes the need for a formal hearing. Lack of agreement in the prehearing conference will not prejudice the case should the Board hold a formal hearing.

In preparing for disciplinary action, the Board of Pharmacy has available for support the Pharmacist Rehabilitation Committee of the Maryland Pharmaceutical Association. The members of the Committee are the experts the Board turns to for advice. For example, at

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Scheer is Executive Director, Maryland Board of Pharmacy, and Dorsey is Executive Director, Maryland Board of Examiners of Nurses, 201 West Preston St., Baltimore, MD 21201

Major portions reprinted with permission from the Maryland Medical Journal the time of a prehearing conference the Board may not have sufficient information to determine whether it is safe for the pharmacist to practice. The Board can refer the pharmacist to the Rehabilitation Committee, which arranges for a thorough evaluation and a report with recommendations indicating whether it is appropriate for that individual to practice. If the evaluating therapist recommends that the pharmacist be allowed to practice, any special conditions of practice, as well as treatment and monitoring suggestions, are included. With this information, the Board is prepared to make a determination.

Unlike the Board of Pharmacy, the Maryland Board of Nursing currently has no link with an impaired nurses committee. The Maryland Nurses Association is in the process of establishing such a committee to provide support to the impaired nurse. In the interim, the Board refers nurses directly for evaluation when information is needed regarding the nurse's plant of treatment and ability to practice.

Once all the necessary information has been obtained, a consent order can be negotiated with the licensee. The order specifies each condition the individual must follow. These conditions are designed to safeguard the public while permitting the professional to practice. Both parties must agree to all aspects of the order, including the findings of fact and the conclusions of law. Usually the order will suspend or revoke the license, stay that action, then place the individual on probation. Some consent orders revoke or suspend the license without a stay until the Board determines the licensee can safely return to practice.

Probation Conditions

Although each order is tailored to the licensee's particular situation, there are a number of common conditions of probation used by both Boards. For example, the licensee must enroll in an approved drug and/or alcohol treatment program. Quarterly reports from the program, indicating that the licensee is complying with all aspects of the treatment plan, are required. Should the licensee be discharged, the program must submit a discharge summary. If at any time the licensee fails to comply with the treatment plan, the program is required to report this to the Board. Observed random urine screens are required with any positive urines reported to the Board. All orders require the licensee to write quarterly reports describing progress being made in coping with the problems of impairment and the licensee's evaluation of his or her own practice. A review of these reports usually provides a strong indication of the individual's progress toward recovery.

The Board of Pharmacy further requires that the pharmacist give a copy of the order to all of the licensee's pharmacy employers and provide the Board with written proof of receipt containing a statement that each employer agrees to comply with the conditions pertaining to that employer. Some orders require the employer to conduct specific periodic audits of certain controlled substances. Each licensee must arrange for all of his or her pharmacy employers to provide quarterly written reports to the Board. Pharmacists who are employed at the time an order is developed usually expect they will be fired. This expectation is inconsistent with the Board's experience. Most individuals are surprised at the amount of understanding displayed by employers when the pharmacist is open and honest about the substance abuse problem. The employer then becomes part of the support system. In addition, monitoring by the employer becomes part of the early warning system designed to protect the public.

The consent order specifies that the pharmacist sign a contract with the Rehabilitation Committee setting forth the performance standards during the probationary period. The Rehabilitation Committee provides quarterly reports that advise the Board of the pharmacist's progress in therapy and in dealing with chemical dependence. If the pharmacist terminates the contract with the Rehabilitation Committee without being discharged, the Board is immediately notified. If it is reported to the Board that the licensee is incapable of practicing pharmacy, the individual will voluntarily discontinue practice until it is determined that the licensee is capable of resuming practice.

The Board of Examiners of Nurses uses a number of conditions designed specifically to assure safe nursing practice. The nurse must inform all of his or her nursing employers of the conditions and arrange for quarterly reports from the employers evaluating the nurse's practice. Work performance has been an excellent indicator of the nurse's compliance with the treatment plan. The Board may also place limits on the type of setting in which the nurse may work. Board approval is required for all nursing employment. This assures that adequate supervision of the licensee is available and that the work setting does not place the nurse at a high risk for failure. Some settings, such as intensive care or emergency, produce a high level of stress which could compromise recovery. The types of drugs the nurse administers may also be restricted until the Board determines it is appropriate to remove the limitation.

All conditions of probation may be amended as circumstances change. The licensee may request, in writing, an amendment and provide rationale for the request. The Board also can initiate an amendment. Because this is a consent order, the Board and licensee must agree on any changes.

As long as the licensee continues to comply with all terms of probation the stay remains in place. Should the licensee violate any condition, after a hearing, the Board may remove the stay and revoke the license to practice. Pharmacy consent orders authorize the Board to suspend or revoke a license without a hearing if the Board receives an unsatisfactory report it believes in good faith to be accurate or if the pharmacist has violated certain sections of the law. However, the pharmacist has a right to a hearing within thirty days of a written request to the Board.

Both Pharmacy and Nursing consent agreements provide for the licensee to petition for termination of probation and full reinstatement without any conditions or restrictions two to five years after the date of the order. When the petition is submitted, the licensee may meet with the Board, submit additional information for consideration, and bring witnesses to testify. Then the Board will compare what actually occurred during the probationary period with each requirement in the order. In most cases the license will be fully reinstated. However, if the Board determines that termination of probation and complete reinstatement is not appropriate, the Board may modify one or more of the conditions or probation. If the licensee does not submit a petition, the probationary status (subject to the conditions enumerated in the order) will continue indefinitely.

Both Boards believe that probation is an effective mechanism for dealing with the impaired professional. The terms of probation permit the Board to carefully monitor the practice of the licensee. Each condition of probation is included because it is an integral part of the mechanism that protects the public and supports the licensee.

Not all nurses and pharmacists who are impaired are reported to their respective Boards. Nurses have the option of enrolling in a drug and/or alcohol treatment program. Should the nurse fail to meet all the conditions of the treatment program, a report to the Board is required. At that point, the nurse is subject to disciplinary action.

Any pharmacist with a substance abuse problem can avoid involvement with the Board and obtain help without jeopardizing the health and welfare of patients. The Board of Pharmacy strongly recommends that the substance abuser sign a contract with the Rehabilitation Committee immediately. The contract specifies the terms under which the Rehabilitation Committee agrees to assume the advocacy role on behalf of the pharmacist. A Pharmacist who has a contract with the Rehabilitation Committee can practice only if the Committee has given approval in writing. Failure to comply with the terms of the contract is ground for release and the matter is referred to the Board of Pharmacy for possible disciplinary action. If the pharmacist complies with the agreement and does not get into legal difficulties, the Board will never be aware of the problem. The advantage to the individual is that the substance abuse never becomes a legal problem and is treated only as a medical problem. The Board views the Rehabilitation Committee as a viable alternative to disciplinary action.

The Boards of Nursing and Pharmacy believe the current disciplinary process is effective in protecting the public. The close monitoring required in the consent order facilitates the Boards' ability to carry out their responsibilities while allowing the licensee to practice under controlled conditions. It is the Boards' view that a nonpunitive approach to the substance abuse problem best serves the public interest.

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Clues to Impairment in Pharmacists

Recently the Maryland Pharmaceutical Association in cooperation with the Maryland Board of Pharmacy has established a Pharmacists Rehabilitation Committee. This committee is now accepting referrals from pharmacists and others where there may be a problem with drug or alcohol abuse. In order that you may be better able to recognize an emerging problem in a colleague or friend, we are publishing these clues from Charles L. Whitfield, Baltimore, Maryland, 1983. Although originally for use for physicians, we have modified them so they may be more appropriate in a pharmacy setting.

Clues to Impairment in the Pharmacist (Early Signs marked with *)

Home and Family

*Medicinal use of alcohol or drugs
*Mood swings or inconsistency
*Behavior excused by family & friends
Extreme temper
Heavy Drinking
Drinking or using activities more important than other activities
Children neglected, abused, or in trouble, often with drugs
Fights, arguments & violent outbursts
Sexual problems
Withdrawal, isolation & fragmentation of social & family life
Family isolating itself from social supports
Financial problems
Spouse in psychotherapy or taking psychoactive medication
Lack of problem resolution
Separation or divorce

Pharmacy

*Overwork
Disorganized schedule
Spasmotic work pace
Unreasonable behavior
Inaccessible to patients & employer
Prescription errors
Patient complaints
Frequent absences
Decreased workload — tolerance
Frequent days off for vague reasons
Taking sexual advantage of co-workers or customers
Filling illegal prescriptions
Taking and/or using drugs from pharmacy without a legal prescription or without follow-up by a physician
Taking and selling drugs to others or giving them to family or friends

Employment Applications

Frequent job changes or relocations
Unusual medical history
Vague letters of reference
Inappropriate qualifications
Time lapse unexplained in work
Inappropriate job now
Refusal of physical exam or spouse interview

Physical Status

*Insomnia
*Personality & behavior changes
*Amnesias
Multiple physical complaints & Illnesses
Frequent ER visits & hospitalizations
Inappropriate tremulousness or sweating
Poor hygiene & appearance
Long sleeves in warm weather

Pharmacy

Often late, absent or ill
Decreased work performance
"Pharmacy gossip"
Unavailability
Alcohol on breath while in pharmacy

Friends and Community

*Neglected social commitments
*Embarrassing behavior
Personal isolation
Overreaction to criticism
Exaggerates work accomplishments & finances
Drunk driving arrests
Legal problems
Neglected social commitments
Lessening of ethical values
Unpredictability or unreliability

Call (301) 727-0746 for information or referral service for the Pharmacists Rehabilitation Committee. The Committee is active and taking referrals.

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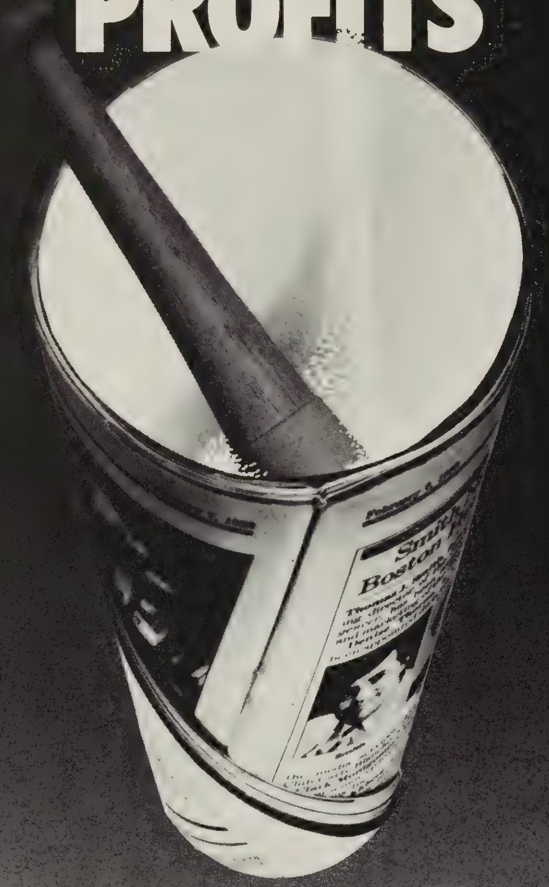

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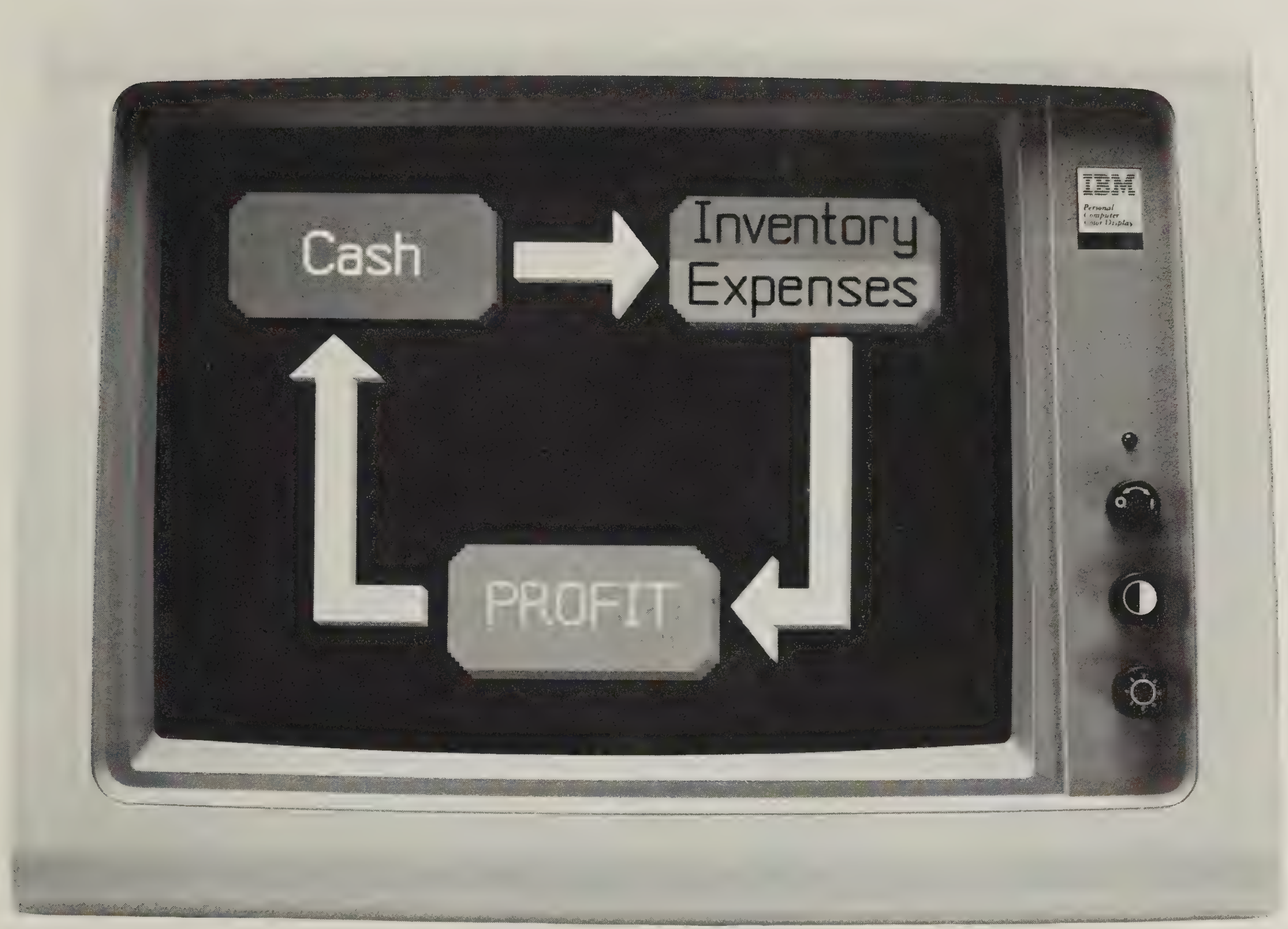

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MPhA Continues A New Member Service and Journal Feature

The patient education aid on the right is part of a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, MD. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

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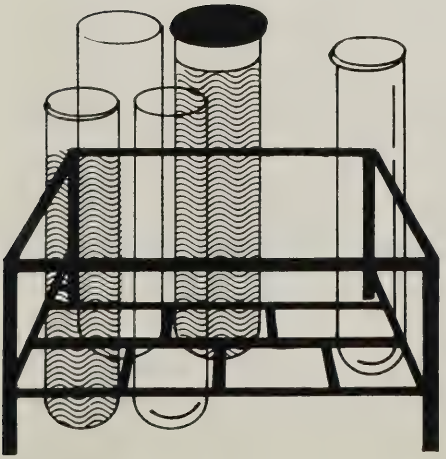
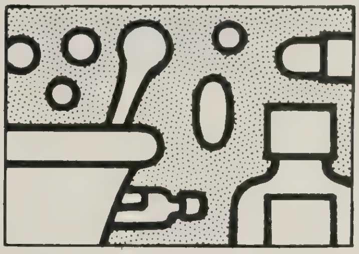


Things You Should Know FOR YOUR GOOD HEALTH



A Hot Weather Warning For Older People

Although summer is traditionally a time for outdoor recreation, the National Institute on Aging warns that hot, humid weather may pose severe health problems for a great many people. Older people, particularly, should take necessary steps to lessen the risks of heat-related illness.

Heat stress, or hyperthermia, can take several different forms from the potentially fatal heat stroke to a less serious heat fatigue. The two most common forms of heat stress are heat stroke and heat exhaustion. Of the two, heat stroke is especially dangerous and requires immediate medical attention.

Regardless of outside temperatures, the healthy human body maintains a temperature in a range close to 98.6 degrees Fahrenheit (37 degrees Celsius). In hot weather or during vigorous activity, the body perspires. As the perspiration evaporates from the skin, the body is cooled, maintaining its normal temperature. If challenged by long periods of oppressive heat, the body may lose its ability to cool itself. Even when the weather is not extremely hot, older people may be more subject to heat-related conditions because of certain health and environmental factors.

People taking diuretics, sedatives and tranquilizers, anticholinergic drugs, and some heart and blood pressure medication which alter the ability to sweat should be aware of the increased risk of hyperthermia. It is important, however, that people taking these medications continue to do so and discuss possible problems with a doctor.

Heat stress can be experienced in different degrees. Heat fatigue is a feeling of weakness brought on by exposure to extreme heat. Heat syncope is a sudden dizziness often experienced after exercising in the heat by people who are unaccustomed to hot weather. Heat cramps or muscle spasms in the abdomen, arms or legs, are often felt after strenuous activity. They are usually caused by salt depletion, although people are advised against taking salt tablets without first asking a doctor.

Heat exhaustion is a more serious warning that the body is getting too hot. It is probably the most common form of heat-related stress caused by the body's loss of water and salt. Heat exhaustion may be treated in several ways. The victim should lie down in a cool place, preferably one that is air-conditioned, and be given fluids. Avoid alcohol and caffeine. Water and fruit and vegetable juices are best. Encourage the individual to shower, bathe, or sponge off with cool water. If left untreated, heat exhaustion can progress to heat stroke.

Heat stroke can be LIFE-THREATENING! Immediate medical attention is required. The death rate for unattended heat stroke approaches 100 percent. If someone you know exhibits signs of heat stroke, emergency medical assistance is essential.

It is easy to avoid heat-related illnesses by simply following some basic, common sense procedures:

- Drink plenty of water and juices.
- Bathe or shower frequently using cool water.
- Wear light-weight, light-colored, loose fitting clothing; cotton is best.
- Avoid vigorous outdoor activity during the hottest part of the day (noon to 4 p.m.). Wear a hat or use an umbrella when out in the sun.
- Use fans and air conditioners liberally. If no air conditioner is available, keep shades or curtains down during daytime hours and windows open at night.
- Avoid heavy meals. Limit the use of ovens.
- Stay in an air-conditioned place on especially hot and humid days, particularly when there is an air pollution alert in effect.

With good, sound judgment and knowledge of preventive measures, the summer can remain a time of fun and leisure for everyone.

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New Column

The Pharmacist and Hospice

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III
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**IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?**

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

First some history. . . .

Many familiar with the concept of hospice are aware that the first hospice program began at St. Christopher's in 1967 in a suburb of London. Dr. Cicely Saunders was the founder. She was, as she described herself, "a nurse with extras".

The original hospice played on the meaning of its name—a stopping place for travelers. It provided its patients every opportunity to live until the last moment of life and then to have a dignified death. Dr. Saunders and her staff believed that all aspects of the patient's being—physical, emotional, social and spiritual—need to be considered in enabling the patient to enjoy the highest quality of life possible.

The modern hospice is an innovative and interdisciplinary program for the care of the dying person and his/her family.

It's purpose:

—treat the person, not the disease
—emphasize *quality* of life rather than prolonging life
—include family in all aspects of care

New hospice programs are being implemented all over the country, giving pharmacists an opportunity to become involved not only in institution-based hospice programs, but home hospice programs as well.

Areas of involvement include:

—Establishing direct working relationship with hospice programs. By establishing such relationships, the pharmacist can provide an important link in the overall care of the hospice patient. Obtaining narcotic analgesics remains one aspect of hospice care that is important, yet poses major obstacles in many instances.
—Providing drug information and counseling for the patients and families.
—Monitoring patients for adverse effects of drug therapy. This can be done on a formal or informal basis. Keeping patient profiles would allow pharmacists to detect the many drug interactions which can occur in these patients and provide a quick overall view of current drug therapy.
—Providing medical devices and appliances that are often ncessary to the hospice patient. Although the pharmacy which participates in the hospice program may not have all equipment on hand, the pharmacist could have names and phone numbers of suppliers that do, facilitating the task of obtaining such items.

—Contractual agreements with the hospice program to act as a consultant. Such agreements could include the attendance at patient care meetings which give the pharmacist the opportunity to be directly involved in drug therapy decisions. Also included could be home visits when needed, and providing inservices to nurses and associated health professionals.

Since this is a growing field, the opportunities for pharmacist participation are still undefined and provide an interesting challenge to our health profession.

Helpful Hints for Involvement with a Hospice Program:

1. Develop and maintain a library of material relating to hospice care, including drug references, journals or articles relating to hospice, and names and phone numbers of referral agencies which may be useful.
2. Maintain patient profiles on all hospice patients. The participating Hospice pharmacist should routinely review and update patient profiles when filling a hospice patient's prescription. Information should include all discontinued drugs (not usually included on most profile records) and any comments regarding adverse reactions to drug therapy. This might necessitate more personal and frequent contacts with the patient and family.
3. Inform the hospice program of the current laws regarding the dispensing and obtaining of Schedule II drugs. Nurses and some physicians may not be familiar with the details of such laws.
4. Inform the local Drug Enforcement Administration office about your participation in the hospice program.
5. Inform the hospice of the total care services your pharmacy is willing to provide. This can range from dispensing prescriptions and delivery service to providing formal consultations.
6. Inform area hospitals, including pharmacy departments, that your pharmacy is available to the hospice program.
7. Be available to physicians, nurses, patients, and other hospice staff who may have need of your expertise.
8. Participation in patient care meetings would be valuable for many reasons. It makes the pharmacist visible to all participating staff. Once they know your face and name, they are more likely to call you with questions. Involvement enables you to understand the dynamics of the entire process. Finally, attendance at such meetings allows active participation in drug therapy decisions.

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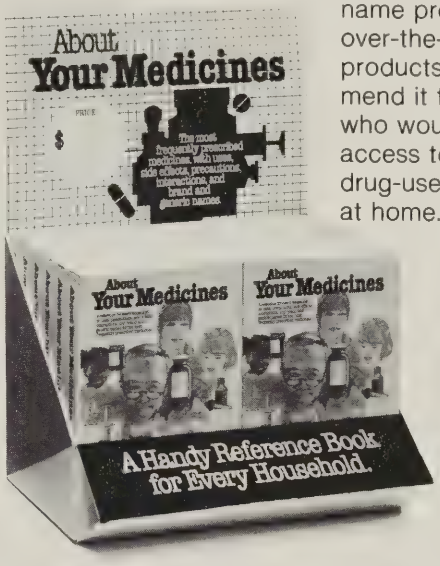
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Employer Power

by Jim Dickinson

Employer power. A recent column entitled "Pharmacy Power" addressed dispensing physicians and ways that pharmacy will win that fight.

Now let's focus on another, even bigger fight, and who will win it. It's the hot war between corporate employers on the one hand and their soaring health costs on the other, paid either through (a) insurance premiums or (b) their own in-house programs.

The employers' dilemma was well-put at the American Pharmaceutical Association annual meeting in Chicago by consultant Laird Miller (Health Systems Management Inc., 612-729-1733), who until recently ran the employee benefits programs of Honeywell, Inc.

"Corporate actuaries worry us with their projections of life expectancies in the 85–90 range and better," he said, referencing the burgeoning number of retirees getting health and drug benefits. "Our chief concern is that we aren't getting value for our money from the health programs we use; we can't pass on an 11% increase in the health cost index, when our customers are holding us to 2% in the price increases they're willing to pay us."

And if you think pharmacists are fed up with third-party payors and insurance programs that (eventually) pay them, corporate employers who buy their programs are even more fed up, Miller says.

Pharmacists formed PSAOs to get the kind of combined clout they need with the programs, and that's what Miller says employers are doing, too.

Small employers, especially, "can buy better when they network with each other."

But listen to what a few large employers did, when they ran up against insurance company arrogance and unresponsiveness.

Without naming names, Miller said he knew of one corporate employer that got so frustrated trying to find out why its health premiums kept rising so much that it did some detective work until it found out the identities of some other customers of that same arrogant insurance company.

They formed an ad hoc "user's group" among themselves, and went in a body to the insurance company, which suddenly became very attentive.

Now the members of the user's group are in the driver's seat with the insurance company, which has agreed to tailor specific health programs for each of them, instead of persisting with its usual and all-too-common attitude of "here's-what-we've-got, take-it-or-leave-it."

This tactic is completely turning the tables on how health benefits are paid for, and is in essence turning the employer into the main regulator of health care today, Miller says.

Now employers can design their own health packages, and dictate the individual provider specifications within those health packages.

Such employers will be more responsive to quality-based arguments than aloof, distant insurance companies and HMOs could be. They will want to deal with local pharmacies—not mail-order (although they will look at all options). They will find employee satisfaction a persuasive argument in establishing program specifications.

And if they get too much resistance from HMOs and other third parties on the adoption of their specifications, they will self-insure, keeping costs down with controllable employee incentives not to overuse services.

Smaller employers will network among themselves—Miller calls it "linkage"—so that they can bring leverage to bear against third parties, HMOs and, yes, even against PSAOs.

'I know if I walked up to you with a quarter-million lives in our pocket, you'd do handsprings to get our business," Miller told his pharmacy audience at APhA.

But with all that leverage and clout and muscle, the employers have a great weakness, he admitted. "They don't know enough about the delivery system, and they need your help."

Sounds like a match made in heaven!

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Editor's Note: Be sure your Pharmacy has joined the Prescription Network of Maryland, the MPhA sponsored PSAO. Contact the office for details.

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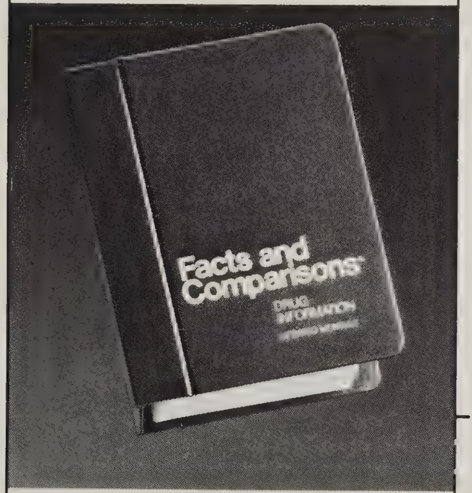

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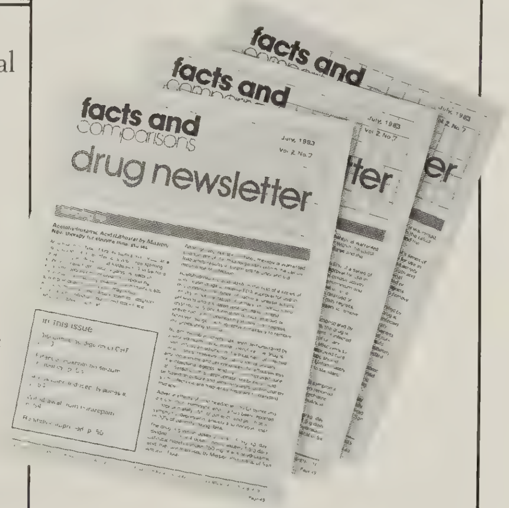

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Determining Perceptions of Over-The-Counter Medication Use in the Elderly

Judy McKay
Thomas LaMartina
Dr. Alan McKay
University of Maryland
School of Pharmacy

The purpose of this project was to obtain a better understanding of the way in which Over-The-Counter (OTC) products are perceived, the dangers associated with their use and the impact physician, pharmacist and other health professional recommendations have on the use of these products. This information will then be used to aid pharmacists in patient counseling and lead to better methods for patient OTC monitoring. To obtain this information, the focus group methodology was used. Two groups were chosen: a group of residents in a nursing home setting and an independently living elderly who attended a senior center. A moderator prompted the discussion with a list of topics to be discussed but the opinions expressed were those of the elderly participants. The purpose of the discussion was to generate qualitative information which could then be used for further study. The individuals from the domiciliary setting were insulated from all aspects of the OTC marketplace: they viewed very few ads, talked only to their physician concerning symptoms (not specific products), did not have control over purchasing decisions and had no contact with a pharmacist. The independently living elderly had more control of their OTC use. Like the institutionalized elderly, they also went to their physician for recommendations, but indicated that this was in reflection of their concern for other existing medical conditions. They thought that the pharmacist was knowledgeable about OTC products but still viewed him as a business man. For this reason and their perception of his unawareness of their other ailments, they used him basically as a source of price comparison and secondary product selection. As a result of the group discussions, two major concerns were expressed. Both groups expressed a strong desire to receive more information. They not only wanted to know the name of the medication, what it was for and the expected side effects but also basic information on how it works and how they can better control their medical conditions. Physicians, pharmacists and nurses were cited as sources of information but their inadequacy led several participants to reference material in local libraries. Pharmacists, therefore, need to convey to this population that the pharmacist is qualified to provide information and as a professional responsibility will either supply it or lead the patient to an appropriate resource. Another concern was the notable absence of the pharmacist in the institutional setting. The pharmacist should be concerned that, with a growing elderly population, a large number of patients will receive drug products without the involvement of the pharmacist. This would result in the loss of a significant market for the pharmacist's services and seriously limit the important patient care contributions that a consulting pharmacist may provide. Studies have indicated that pharmacist's, working closely with physicians in other patient care settings, optimize the care received by patients. This type of involvement was not evident in the two settings studied.

Introduction

Current technology has increased the life span of the average American so that the elderly (65 years and older) population is increasing drastically in both number and in proportion to the other age groups. In 1983, 1 in 9 Americans were in this category and this number is expected to increase to 1 in 5 in the following 20 years. Due to an increased amount of medical ailments in this population, these individuals represent an area of increased concern in the field of medical care. The elderly account for a significant amount of prescription drug use, but, because of limited medical coverage or because of the perception by individuals that some ailments are self-limiting, a great number of problems are self medicated. Self medication may be viewed as a substitute for or an adjunct to qualified medical care. Physicians recognize this tendency and may on occasion urge patients to use available Over-the-Counter (OTC) medications as a cost saving measure or because of their effectiveness. Concern has been raised, however, over the potential for misuse of

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Study conducted under a grant from the National Association of Retail Druggists Foundation

these medications and specifically over the possible over use of certain products.

A better understanding of the way in which Over-The-Counter medications are viewed by the elderly . . . the dangers associated with their use and the impact physician, pharmacist and other health professional recommendations have on the use of these products could enhance educational efforts and lead to better methods for Over-the-Counter medication monitoring.

The objectives of this study were to identify and contrast the perceptions of Over-The-Counter products in the independently living elderly with those in an institutional setting. The two hypotheses for this study were that the independently living elderly would differ from comparable institutionalized individuals in terms of: (1) involvement in selection of over-the-counter products and, (2) awareness of the role of health professionals in the selection and use of over-the-counter products. Factors to be studied were general perceptions of OTC products, the dangers associated with their use and the influence of health professionals' recommendations.

Methods

The Focus Group Methodology[1] was selected as appropriate to the qualitative goals of this project. Focus groups usually consist of 8–12 participants in an informal discussion guided by a moderator. Group participants were selected on the basis of individual characteristics that were reflective of the demographics (Table I) of elderly individuals. Two groups of individuals were recruited representing two distinct elderly populations: the independently living elderly and patients in domiciliary care.

Before the start of each focus group meeting a short questionnaire concerning participant demographics and use of over-the-counter products and health professionals was distributed. Individuals requiring assistance (blind and infirmed) were assisted by the project staff.

An outline was prepared to guide the discussion and to insure that the desired topics would be covered. The moderator introduced each topic with a question and kept the discussion within the desired limits. When this topic was sufficiently covered or the discussion seemed to be getting off the track, a new question would be addressed. The informal setting of the focus group encouraged spontaneous interchange among the participants resulting in the expression of opinions and perceptions that would not have emerged through direct questioning.

Notes were taken during the discussion by two observers. They were then organized to parallel the discussion guide, analyzed for relevant information, and finally comparisons and contrasts between the two groups were compiled.

Results of the focus group project have been separated into results of the questionnaire (TABLE I—Demographics; TABLE II-OTC and Health Professional Use) and results of the focus group interviews (TABLE III). Results of the focus group interviews were placed in parallel columns to facilitate comparison of the responses.

Conclusions and Observations

Participants expressed several areas of concern for pharmacists. Individuals in both the independently-living group and the institutionalized group expressed the desire to know more about the medications that they are taking. This seemed to be particularly important to the individuals in the institutional setting as they had no knowledge of what medications they were taking and no distinction between prescription and non-prescription products. They wanted more information as to the name of the product, what it was used for, side effects, how it works and how they can better control their medical conditions. Physicians, pharmacists, and nurses were cited as sources of information but their inadequacy led several participants to reference materials in the library. Pharmacists, therefore, need to convey to the public that they are qualified to provide this information and as a professional responsibility will either supply it or lead the patient to an appropriate resource.

Another concern was the notable absence of the pharmacist in the institutional setting. The pharmacist

TABLE 1
Demographics

	Institutionalized		Independently-living	
Mean age		81		66
Race	Black	10%	Black	15%
	White	90%	White	85%
Married	Single	2	Single	5
	Married	0	Married	0
	Widowed	6	Widowed	1
Income	<$5000	80%	<$5000	71%
	$5–10,000	20%	$5–10,000	29%
Education	Grade school	70%	Grade school	43%
	High school	30%	High school	14%
	College	0%	College	43%

TABLE 2
Introductory Questionnaire

	Institutionalized		Community-living	
Do you use OTC's regularly?				
	Yes	3	Yes	5
	No	4	No	2
Are you responsible for purchasing your own OTC's?				
	Yes	1	Yes	6
	No	4	No	1
Do you have a regular pharmacy that you use for a majority of your prescription and non-prescription needs?				
	Yes	0	Yes	7
	No	6	No	0

should be concerned that, with the growing elderly population, a large number of patients will receive drug products without the involvement of the pharmacist. This would result in the loss of a significant market for the pharmacist's services and seriously limit the important patient care contributions that a consulting pharmacist may provide. Studies in other areas have indicated that the pharmacist's working closely with physicians in other patient care settings, optimize the care received by patients. This type of involvement was not evident in the two settings studied.

REFERENCE

1. Higginbotham, J. B. & Cox, K. K., *Focus Group Interviews: A reader,* American Marketing Assoc., Chicago (1979).

TABLE 3
Focus Group Results

	Independently living elderly	**Institutionalized elderly**
	Participants in this group were senior citizens attending a senior center in downtown Baltimore. Membership was open to all elderly residents (60 and older) in Baltimore. The center provided a wide variety of educational, recreational and nutritional services including a hot meals program, social, legal and medical services. Participants were charged a nominal annual fee that was supplemented through city, state and federal funds.	Participants were chosen from a private, long-term care facility located in the city of Baltimore. This 283 bed facility was a component of a religiously supported institution. Services included chronic and acute medical care, rehabilitation care, group home and adult day care.
Do you use Over-The-Counter (OTC) medications regularly?	Several of the participants stated that they regularly used some OTCs particularly pain relievers (ASA, Tylenol, etc.) and medications for colds or allergies. Less frequent use was made of insulin and other products. Availability was a major benefit of using OTC's in the independently living elderly, especially since a visit to their physician was not required. This was also a major cost consideration.	The patients did not seem to perceive the difference between prescription and OTC's. They listed OTC's as regularly used but included them in their listing of all products consumed. The lack of knowledge concerning OTC's was in part a reflection of their lack of control over the selection of OTC's since patients were expected to present symptoms to their attending physician and he would "prescribe" the appropriate medication for the "problem."
Does advertising influence your selection or requests for OTC products?	Participants indicated that they saw advertising through various media but these served only as an introduction to the product and were not considered a major factor in the final purchasing decision. Most of the advertisements were viewed as promotional, however, several participants indicated that they would like to see more information in future advertisements.	Participants did indicate that they were exposed to advertising through newspapers, television and magazines. Occasionally they did ask their physician about a product they saw in an advertisement, but they were not sure if they were receiving that product.
From whom do you first seek advice when you need an OTC recommendation?	Members of this group indicated that they first seek the advice of their physician. With further questioning it became apparent that their reason for doing so was because of the physician's awareness of their other conditions and not because they felt he was more knowledgeable. (Participants felt that pharmacists were more knowledgeable regarding over-the-counter medications). Little or no discussions were made with the nurse, friends or family.	Because of the lack of access to the pharmacist, the participants in this group seek all their advice from their physician. However, occasionally, they do ask him for a particular product by name but were unsure if the product was indeed the one which they requested or if it was a substitute. Prior to their institutionalization and when they were healthier, they did seek the advice of the pharmacist, often before seeing their physician. Several participants reminisced about the times they went to see "ole' doc on the corner."
What do you talk about?	Participants indicated that they present their symptoms to their physician and he makes the decision on whether or not to recommend an OTC product. They felt that the physician had no concept of prices but did not indicate that they specifically asked their pharmacist for an appropriate alternative. Many indicated that they compare prices and use generic or store brands.	Participants in the institutionalized group indicated that when they request a product from their physician, no further discussion takes place other than why they are requesting the product.
How often do you see your physician?	Members of this group indicated that they see their physician at least every 60 days. Those with more severe conditions saw him more frequently.	Participants in the institutionalized group see their physician once a month in the absence of acute problems.
How often do you see your pharmacist?	Visits to the pharmacist are made at least twice as often as those to the physician.	Members in this group do not have access to a pharmacist anymore.
Do you think that physicians or pharmacists are more knowledgeable about OTC products?	Members of this group definitely thought that pharmacists were more knowledgeable about OTC medications, especially regarding the various types of products available, including equivalent products, price, effectiveness and proper use.	This group expressed no opinion on this topic.

In general, how would you describe the counseling you receive from your physician, pharmacist and nurse? (Nurse pertains to those in the institutionalized setting because she administers their medication)

Independently living Elderly	Institutionalized Elderly
Members of this group expressed a strong desire for more information about their medications. Often when they ask their physician about the use of a certain medication, they were referred to the pharmacist. However, often times, they were referred back to their physician. This vicious circle frustrated several members of the group. One of the members of the group had recently been discharged from a hospital and was really impressed with a nurse who counseled him on the use of his medications he was discharged with. So strong was the desire for more information that several members indicated that they made trips to the library to find information, often from professional references, as opposed to those written in lay language.	Participants in this group indicated that they received very little information from either the doctor or the nurse. Because of their complete trust in their physician, they did not feel that this was a problem with him. (Perhaps they did not feel that it was his duty.) However, a negative opinion was expressed towards the nurse. They felt that she just handed them their medications, told them to take and watched them until they did, without comment.
Suggestions for improvement in use of OTC's 1. *Better labeling*—Several members indicated that they had problems reading fine print on bottles and packages. A suggestion was made to use package inserts in OTC's which were easier to read. 2. *Better information*—Package inserts would also be useful where specific administration techniques are used or where more information about a subject would be appreciated. Several members of the group had conditions where either sodium or sugar restriction was necessary and indicated that this information was often not available. 3. *Child-proof and tamper-resistant containers*—It is not surprising that the elderly were in favor of using tamper-resistant measures, such as film seals around product container or package. However, it is surprising that they supported the use of child-proof containers. They agreed that the benefit of less accessibility by children was worth the inconvenience it caused the elderly.	The institutionalized elderly were isolated from all aspects of the OTC marketplace; they viewed very few advertisements, talked only to their physician concerning their symptoms (not about specific products) and had no control over purchasing decisions. Impressions of OTCs were dated and reflected their personal use prior to institutionalization.

LETTERS

To the Editor:

I am concerned about the diaper rash paste described in the Compounders Corner of the December 1986 issue of The Maryland Pharmacist. The formulation contains boric acid in a concentration which has been found to be potentially toxic. Years ago boric acid was a popular topical antiseptic agent. However, boric acid is well absorbed through denuded or abraded skin and may be absorbed through intact skin. Toxicity and fatalities have been described following ingestion, dermal application and instillation in body cavities. There are numerous reports of toxicity and death resulting from the use of boric acid for diaper rash in infants (1, 2, 3). Consequently the medicinal uses of boric acid as antiseptics and irrigants have been abandoned (4). Boric acid has doubtful therapeutic value and there are more effective and safer drugs currently available. I would hope that a drug which was recognized as being unsafe as far back as the 1950's would not be recommended in the 1980's.

Sincerely Yours,
Wendy Klein-Schwartz, Pharm.D.
Assistant Director
Maryland Poison Center
Associate Professor
Clinical Pharmacy

REFERENCES

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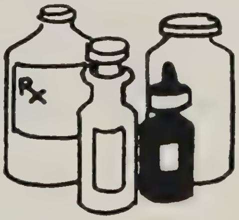

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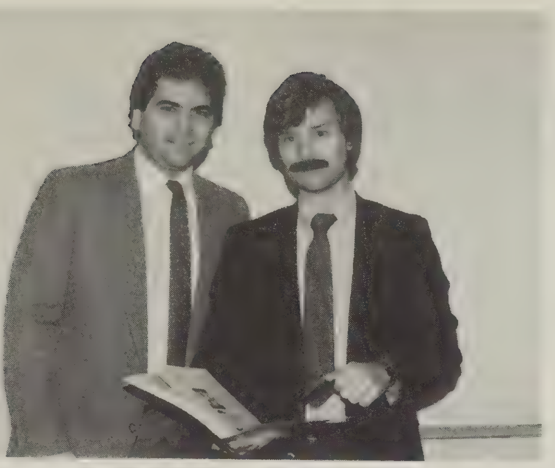
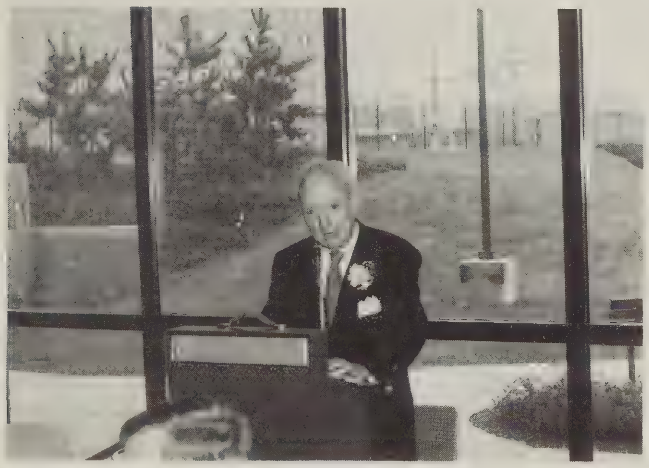


The Continuing Education Coordinating Council's successful March 15th program on "Airway Disease" featured Erkan Hassan (left) as moderator and Robert Feroli (right) as one of the speakers.

Student APhA President Michael Manolakis and USP Executive Director William Heller congratulate the 1987 Patient Counseling Competition Winners. Left to Right are: Manolakis, first place winner Johnathan Schiller, Heller, third place winner Nancy Feuerstein, fourth place winner Julie Scharmann, and second place winner Marcia Anderson. Heller is the MPhA's Honorary President and David Banta, MPhA Executive Director (not shown) served on the judging panel.



Charles Spigelmire was honored by the Baltimore Metropolitan Pharmaceutical Association at a luncheon in the School of Pharmacy for his 32 years of service to the BMPA as Treasurer. Charles responded to the many testimonials given to him on that occasion.

Mary Ann Frank, who is celebrating 25 years as Comptroller for the Maryland Pharmaceutical Association, recalled her years of association with Dr. Spigelmire and also presented Josephine Spigelmire with a special award of recognition.

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The Compounders Corner

by
Loyd V. Allen, Jr., Ph.D., and M. Lou Stiles, M.S.
The University of Oklahoma College of Pharmacy
Oklahoma City, Oklahoma 73190

CARAFATE® SUSPENSION:
Rx Carafate® 1 G.
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(Cherry Syrup, optional) a.a. q.s.

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The Carafate® tablet is placed in the water portion of the formulation vehicle. This combination is then set aside for approximately fifteen to twenty minutes, allowing some time in which to facilitate dissolution of the water soluble materials. Next, the 70% Sorbitol is added to the solution. An equal amount of Cherry Syrup *may* be desirable as a flavoring agent if the suspension is intended for oral administration.

USE:
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LABELING:
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The tablet is first placed in the water component of the vehicle, allowing 15–20 minutes for dissolution. The 70% Sorbital solution used in this formulation is frequently incorporated into liquid preparations as an alternative to using propylene glycol or glycerin. It is classified as a pharmaceutical necessity. It is a clear, sweet solution with no distinguishable odor. The fact that it is about one-half as sweet as sugar provides another reason for its use.

Cherry Syrup, or any other flavoring agent, may be desirable for oral administration.

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

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calendar

June 21–25—MPhA ANNUAL CONVENTION—OCEAN CITY, Maryland

Oct. 9–11—MSHP Annual Seminar, Williamsburg VA

Oct. 18–23—NARD Convention

Oct. 23–25—Post NARD Convention side Trip to San Francisco

Jan. 17–24, '88—MPhA Trip to Curacao in the Caribbean

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"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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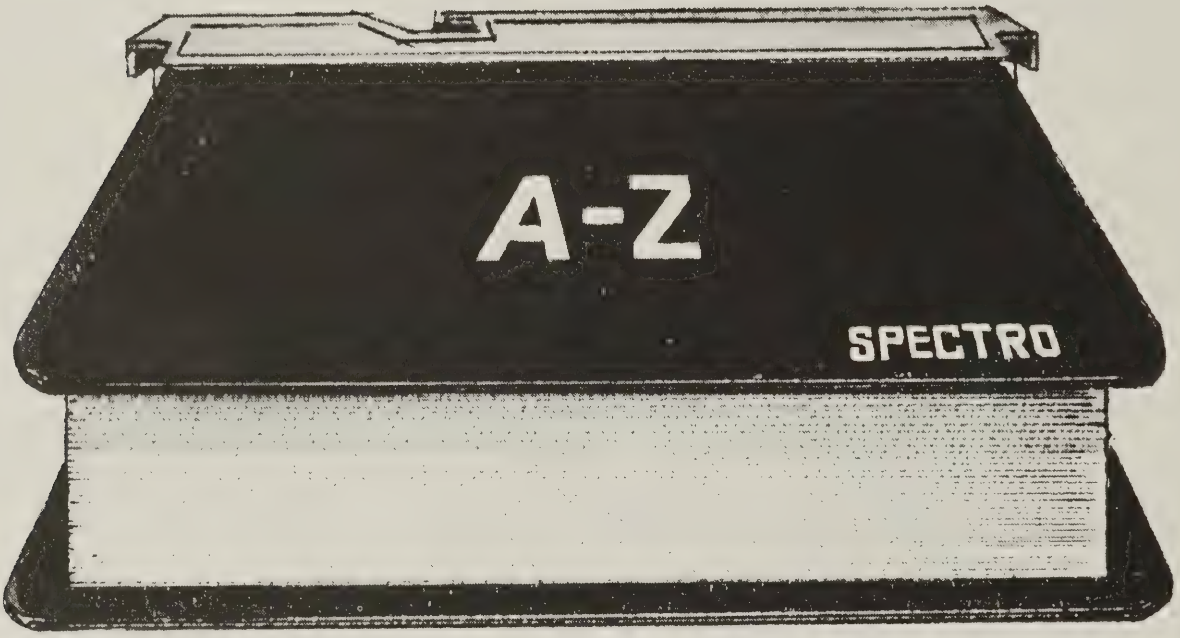

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Official Journal of
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July, 1987
VOL. 63
NO. 7

Ostomies and Ostomates: Diseases and Surgical Procedures

—J. Richard Wuest
—Thomas A. Gossel

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—Diane White
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—Ilene H. Zuckerman

Pharmacist Control over OTC Merchandizing

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Writing Letters: A Commentary

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Giving the Consumer a Say

—Bruce R. Siecker
—Beverly A. Gilbert

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105th Annual Convention President's Report

"All I need is the time . . ." These words from a fairly recent popular song are what come to my mind as I review this past year as President. There is so much to be done and so little time to do it—but, generally, it has been a good year. We have won a few; we have lost a few–others are still up in the air.

Perhaps our greatest victory came with the defeat of the State's intention to implement a new policy of prescription drug reimbursement where—in exchange for a 50-cent per prescription increase—pharmacists were to be disallowed earned discounts. The system worked on a sliding scale—with the state keeping from 1% of the cost of ingredients up to 12% of the AWP. Instead of this totally unacceptable policy which would have cost every retail pharmacy $7,000 over a two-year period (according to NARD figures), we received a 25-cent per prescription increase. Of equal importance, I believe, was the fact that success came through the combined efforts of the MPhA, NACDS, and the NARD.

Last year, one of our major accomplishments was Senate Bill 830, which would regulate physicians selling prescription drugs directly to their patients. The Federal Trade Commission then urged Maryland regulators to encourage doctors to do that very thing. The resultant local and national publicity was overwhelmingly favorable to the pharmaceutical community. This is another battle we are going to win—not just because we are right, but for the public good and in the interest of fair competition.

We are also battling the Hopkins Health Plan, which does not allow most pharmacies to participate. Legislation is being considered on Freedom of Choice. This is another one we intend to win.

The Prescription Network of Maryland has been established as a for-profit subsidiary of the MPhA, so we can actively pursue prescription programs for our members. The PNM is authorized to purchase D and P Processing, which will allow us processing capabilities.

Among this year's positive notes are the following. The Maryland Society of Hospital Pharmacists and the MPhA co-sponsored the first (and, we hope, annual) Art Show and Auction for the benefit of the Impaired Pharmacists Committee. We are happy to report both a financial and social success. Also, the Drug Utilization Review Program was established with Jean Hoffman as its head. The year 1986 ended with a record number of MPhA members. Additionally, our mid-year meeting in Annapolis had record attendance, and we have every reason to believe it will expand more each year. One of our own, Don Elliott, became the first pharmacist in recent history to be elected to the Maryland Legislature. PharmPAC was reorganized with new officers to continue the fine work done by this organization.

It has been a good year! And I would like to thank the people who made it just that—Dave Banta, Beverly Litsinger, Mary Ann Frank, Jean Hoffman, and of course, the Board Members, especially incoming president, Lee Ahlstrom, who I know, will have an even better year. Thanks.

George C. Voxakis, P.D.

Delivered June 23, 1987

Ocean City, Maryland

CONTINUING EDUCATION FOR PHARMACISTS

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. IV, NO. 6

Ostomies and Ostomates — Part I Diseases and Surgical Procedures

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. define terms associated with formation of a stoma; and
2. discuss diseases and disorders that may necessitate the creation of a stoma.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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Objectives

At the conclusion of this lesson, participants should be able to:

1. demonstrate knowledge of pathologic processes that may require formation of a stoma;
2. define specific terms that relate to ostomies and ostomates;
3. differentiate between temporary and permanent ostomy procedures, their functions, and the nature of their discharge; and
4. define an ileal conduit, and exhibit an understanding of how it differs from other ostomy procedures.

An ostomy procedure is the surgical creation of an opening (stoma) of the colon or ileum through the abdominal wall. From 90,000 to 100,000 ostomy procedures are performed in the U.S. each year. There are currently more than a million Americans living today who have undergone this surgical procedure, and are now leading near-normal lives.

Supplying these patients with their required appliances and auxiliary products is one of the least costly and easiest means for pharmacists to enter the burgeoning home health care market. It is also a professionally rewarding endeavor since the ostomate's rehabilitation can be aided by pharmacists who are knowledgeable about their conditions and are willing to offer them the understanding and advice necessary to assure a full and useful life.

This article is the first of two that presents insight into ostomies and the ostomate patient. The series begins with a discussion of pathologic processes that lead to the need for ostomy surgery, and continues by outlining the major surgical procedures that are taken. It continues next month with a discussion of the various types of ostomy appliances available. Advice for pharmacists to pass along to ostomate patients will also be presented.

A glossary of terms that relate to ostomy procedures is presented in Table 1.

Diverticulitis

This term refers to inflammation of diverticula. These are small herniations in the intestinal mucosa, or more simply, small sacs that are caused by ballooning out of the bowel wall. They most frequently occur in the sigmoid region of the colon, and are not normally pathologic. Nearly everyone has them; as people age, more diverticula develop.

Diverticulitis is rare in persons under 40 years of age, but affects approximately 10 percent of persons aged 60 or older. The inflammation usually results from infection of the diverticula or herniated mucosa. Untreated, abscesses may form resulting in further inflammation, thickening of the tissue, and obstruction of the bowel. Within this thickened tissue mass, persistent infection may lead to further complications including abscesses which perforate and release intestinal contents into the peritoneal cavity. If this occurs, death is probable within hours to days.

Oftentimes the milder forms of diverticulitis respond well to treatment with analgesics, antiperistaltics such as Lomotil® or Imodium®, antispasmodics such as Bentyl®, stool softeners, and/or antibiotics. Surgery is necessary if the condition does not respond to medical treatment, if it progresses to abscess or fistula formation, rectal hemorrhaging or septicemia, or if cancer is suspected.

Crohn's Disease

Crohn's Disease (regional enteritis) can affect any portion of the alimentary canal and is often patchy in nature. It is a chronic inflammatory condition marked by periods of flare-ups and remissions.

Table 1

Glossary of Terms

Colostomy: derived from the stems: colon, large intestine; stomoun, to provide an opening; and tome, a cutting operation. Therefore, a colostomy is a surgical creation of a new opening for the colon out of the abdominal wall.

Ileal Conduit: a surgical procedure whereby the urinary bladder is removed or isolated, and the ureters transplanted to a section of resected distal ileum which acts as a collecting pouch for urine. The section is closed at one end, and the open end is brought out of the abdominal wall. Some procedures are performed with a section of colon.

Ileostomy: derived from the stems: ileo, small intestine; stomoun, to provide an opening; and tome, a cutting operation. Therefore, an ileostomy is the surgical creation of a new opening for the ileum out of the abdominal wall.

Ostomate: an individual who has undergone a surgical procedure to produce a stoma in the abdominal wall.

Ostomy: a surgical procedure in which a portion of the intestine or urinary tract is removed, and remaining ends are brought to the skin's surface as a stoma.

Stoma: refers to any opening of the intestine, but in the context of this article, stoma refers to a surgically-created opening in the abdominal wall. It functions to divert urine or fecal waste.

Temporary Ostomy: a bypassing of the bowel for a finite period of time to allow the diseased tissue time to heal. The detour allows the distal segment of intestine to rest, while the proximal portion excretes fecal material.

Unfortunately, most patients develop complications such as obstruction, hemorrhage, abscess or fistula formation, which may require surgery. Hopefully, the affected area of intestine can be removed, and the remainder resected. If this does not arrest the condition, an ostomy procedure will be necessary.

The "fortunate" patient may respond to drug therapy. Antispasmodic or antiperistaltic agents may provide symptomatic relief from abdominal cramping and diarrhea. In milder forms of disease, anti-inflammatory agents may produce remission. One of the bile sequestrant agents (Questran®, Colestipol®) may aid in controlling diarrhea in those patients who develop bile salt malabsorption.

Ulcerative Colitis

This condition occurs predominantly in Caucasians under 50 years of age, usually between 18 and 35. Ulcerative colitis is responsible for approximately 90 percent of all ileostomy procedures.

Ulcerative colitis is a chronic inflammatory and ulcerative disease of the colon of unknown cause. The extent, severity, and prognosis of the disease vary. The condition can onset immediately, but most often occurs slowly and insiduously, starting with mild abdominal cramping, increased urgency to defecate, and diarrhea with bloody mucus and pus in the stool.

Cramping which accompanies ulcerative colitis increases as the condition advances. Bowel movements with watery stools may occur 20 to 35 or more times daily. Varying degrees of fever are present. In less severe cases, individuals experience alternating periods of remission and recurrences. Following a severe acute attack, the victim becomes toxemic, emaciated, and may die suddenly from intestinal hemorrhaging.

In most cases, ulcerative colitis starts in the distal colon near the rectum, and extends upward. In severe cases, the process spreads over the entire colon, and may advance into the ileum, causing loss of function of the ileocecal valve, and preventing proper absorption of nutrients.

The actual cause of ulcerative colitis has not been determined. Many patients are hyperactive and tense, but others are not. An important factor appears to be overuse of stimulant cathartics. The constant irritating action on the intestine prompts active colonic contractions which, over time, may result in a diffusely contracted colon with weakened, damaged musculature. Pathogenic bacteria can then invade the tissue.

Early treatment is primarily medical. Strict bedrest is often required, along with a restricted diet. Mild-to-moderate diarrhea is treated with antiperistaltics. Antispasmodics, sedatives and analgesics are given supportively.

Sulfasalazine (Azulfidine®) is reportedly the agent of choice for treating mild ulcerative colitis. It is degraded in the gut to salicylic acid and sulfapyridine. Salicyclic acid reduces inflammation because of its prostaglandin inhibiting action. Sulfapyridine helps prevent invasion of bacteria into colonic tissue. However, the gut bacterial flora remain virtually unchanged.

Corticosteroids are also used in therapy. Although not curative, steroids induce remissions in approximately 70 percent of patients with mild disease. They are not effective in maintaining remissions, and should be discontinued once the disease is controlled. Long-term steroid therapy is unwise because of adverse effects. An ileostomy procedure may be better for the patient than continued drug use.

Life-saving surgery may be necessary if the patient does not respond to medical treatment, there is massive hemorrhaging, cancer is suspected, symptoms worsen, uncontrollable diarrhea occurs, or the bowel becomes obstructed. An ileostomy is usually required because damage to the large intestine is so extensive.

Cancer

The most common disease requiring a colostomy is cancer of the intestine. If the cancer has not invaded an extensive area of the colon, a temporary colostomy may be possible. In this instance, the cancerous section is removed, and the healthy sections of remaining bowel are brought through the abdominal wall (double-barrel colostomy, discussed later).

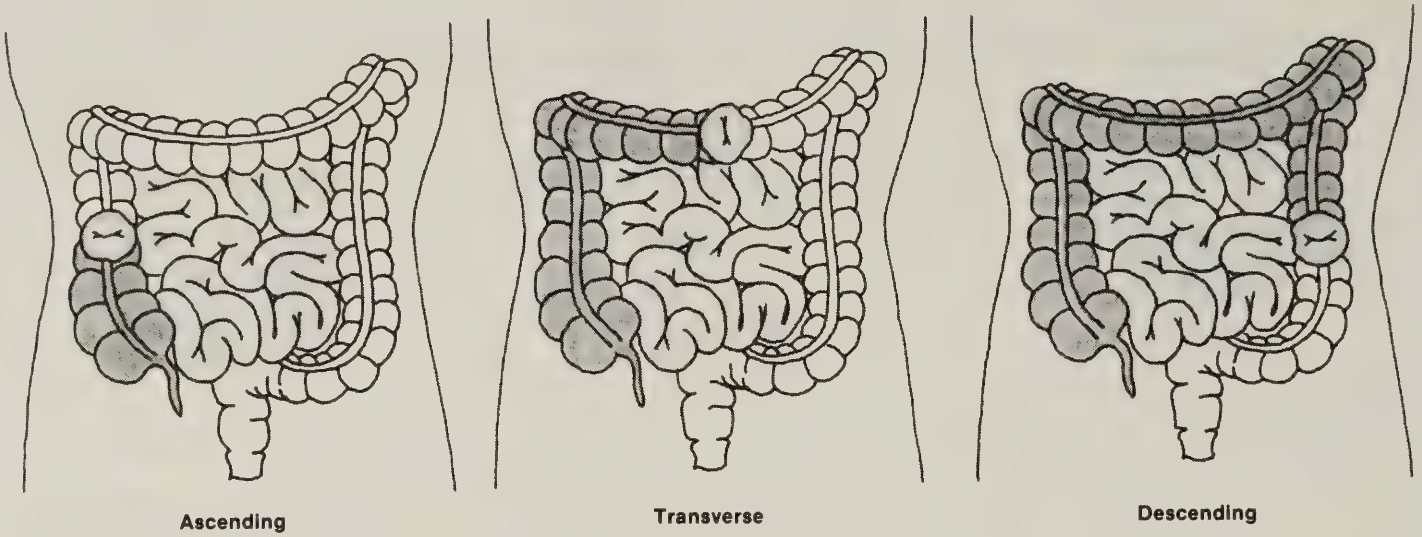


Figure 1. Permanent colostomies

The patient is observed for several months to assure that the cancer has been arrested.

If the cancer is not controlled, the patient returns to surgery and the intact sections of colon are reattached. If the disease is extensive, the portion of bowel distal to the stoma is completely removed and the colostomy becomes permanent.

Traumatic Injuries

When the intestine is extensively damaged due to a traumatic injury such as an automobile accident, the damage may be too extensive to allow closure of the wound. An ostomy procedure may then be required.

Congenital Defects

Occasionally the anal sphincter of a neonate is not sufficiently innervated to function properly. This may indicate the need for surgery because a ballooning out of the rectal tissue can occur, leading to perforation. A temporary colostomy is performed on these infants during the first few days of life. The infant is allowed to develop to adequate weight, and then definitive surgery is performed.

Colonic Obstruction

Mechanical obstruction may occur from tumors within or adjacent to the intestine, entrapment of a section of the bowel within a hernial ring, volvulus (a twisting of the bowel), inflammation, impacted feces, or intussception (telescoping of a segment of intestine within itself).

Neurological obstruction is caused by interference with innervation of the bowel resulting in retarded or absent peristalsis. Paralytic conditions may result from surgery, peritonitis, violent pain, or severe diseases such as pneumonia.

Vascular obstruction results from interruption of the blood supply to a portion of the bowel. This leads to loss of flexion of that section. Thrombosis or embolism of an artery that supplies that area can cause it.

Patients suffering from obstructive conditions often experience severe cramping. This occurs because obstruction causes increased peristalsis above the affected site, in an attempt to move the fecal material downward. Reverse peristalsis, with frequent vomiting, is another symptom.

Complete intestinal obstruction nearly always requires surgical relief. If the damage is not severe or extensive, the surgeon may be able to remove the affected tissue and resect the intact, remaining parts, thus obviating the need for a colostomy. If this is not possible, a permanent colostomy will be necessary.

Ostomy Surgical Procedures

As stated earlier, an ostomy procedure is the surgical creation of a new opening of the colon or ileum out of the abdominal wall to divert feces or urine. The selection of a site for the stoma must be carefully undertaken. It should be away from body folds so that the appliance can be firmly attached.

Colostomies

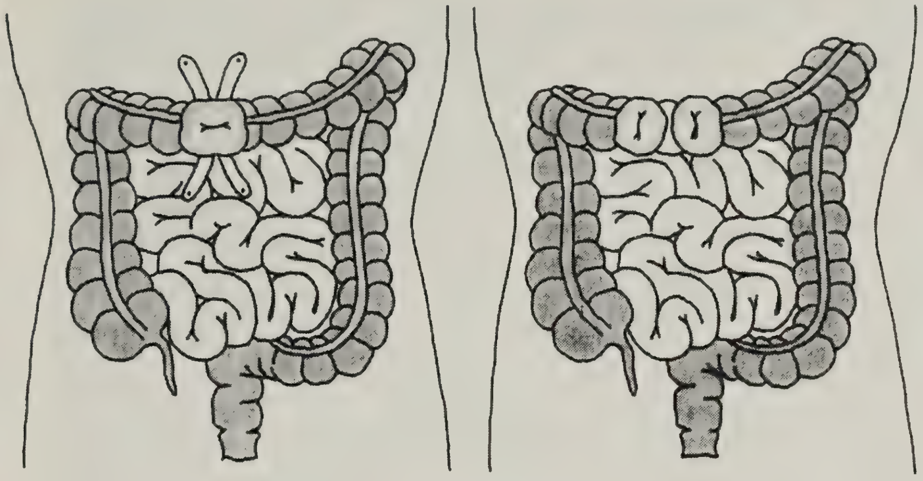
There are two major types of colostomies: permanent and temporary. **Permanent colostomies** (Figure 1) are further subdivided by anatomical location into descending or sigmoid, ascending, and transverse procedures.

Temporary colostomy procedures (Figure 2) include the double-barrel colostomy and loop colostomy.

Descending Colostomy. This procedure is performed when the disease is limited to the rectum or distal colon. The stomal opening is usually made in the lower left quadrant of the abdominal wall, intermediate between the pelvic and mid-body folds.

The descending colostomy is referred to as a "dry" colostomy because the stool at this point is usually solid and formed. Most of the fluid that has been secreted into the gastrointestinal tract has been reabsorbed prior to this point. Although there is no voluntary sphincter control, these patients can often regulate themselves to near-normal movements through proper irrigation of the remaining bowel on a daily or every other day basis.

Ascending Colostomy. This type of colostomy discharges an almost continuous flow of liquid stool. Like



Loop

Double-barrel

Figure 2. Temporary colostomies

the ileostomy (to be discussed shortly), the excretion will contain digestive enzymes and require that the patient wear a drainable appliance continuously, preferably one with a water-tight seal to protect the skin around the stoma.

Transverse Colostomy. The discharge is unpredictable with this type of colostomy. Formed stools are possible, but they will more than likely be semi-solid to watery. Patients require a drainable pouch. Again, the skin around the stoma must be protected from intestinal discharge due to its enzyme content.

Double-Barrel Colostomy. The double-barrel colostomy is so named because the intestine is severed proximal to the diseased portion, and both segments are brought through the abdominal wall. The stoma from the upper portion excretes waste while the stoma of the resting portion may dribble mucus. The two openings are constructed to allow for an appliance to be placed on the proximal stoma without interference from the nonfunctioning one. A gauze pad or stomal cap is placed over the nonfunctioning opening to collect mucus and protect the exposed tissue.

Some surgeons prefer to close the lower portion of the remaining bowel, and place it inside the abdominal cavity. In either instance, the hope is that the two sections can eventually be reunited and returned to normal function after the diseased section has healed.

Loop Ostomy. With this procedure, the intact bowel segment is brought through the abdominal wall and an incision is made along the outer surface of this intestinal loop. The contents will drain from it into an ostomy appliance.

Both of these temporary ostomies are kept open for a period of several months to a year (usually 6 to 9 months) to allow the distal bowel to heal. If the procedure was an emergency or life-saving operation, time is allowed for the patient to recover sufficiently before further surgery is undertaken.

If the diseased section heals satisfactorily, the two ends of the double-barrel ostomy are sewn together, or in the case of the loop ostomy, the incised section is restored and the loop is returned into the abdominal cavity. If healing does not occur, a permanent ostomy is performed.

Ileostomy

An ileostomy (Figure 3) is performed when the entire colon is diseased and must be removed. Most ileostomies are performed on ulcerative colitis patients between 18 and 40 years of age. The ileal stoma must be as distal as possible to prevent complications from food or electrolyte malabsorption.

Ileostomal discharge will be somewhat continuous and rich in digestive enzymes. The stoma may protrude further from the body than from a colostomy because digestive juices that contact the patient's skin would treat it as any other piece of meat. The ileal stoma is made longer to allow its protrusion into an appliance to direct its output away from the skin. A properly fitted, carefully applied appliance is an absolute necessity for these patients.

Protecting the patient's skin is imperative. Ileostomates should watch the stomal site and change their appliance whenever seepage occurs. Also, the proper type of skin barrier should be used.

The ileostomy may occasionally bleed, especially when new. If there is only a small quantity of blood, patients need not be concerned. They can gently pat the area with a soft guaze pad, but should never attempt to clean the stoma with paper towels or a rough cloth. Excessive bleeding should be reported to a physician immediately.

Ileostomies are sometimes refitted from time to time after surgery because of stomal shrinkage. A final fitting for a permanent appliance is made after 3 to 4 months.

Complications may occur during the first few weeks after surgery. The most common include obstruction or infection. Ileitis (inflammation of the ileum) may occur any time, even years after the operation, and should be watched for since the condition may lead to hemorrhage.

During the humid summer months when work or recreation causes excessive sweating, the patient should ingest adequate fluids to prevent dehydration. The electrolyte-replacing drinks, such as Gatorade™, are

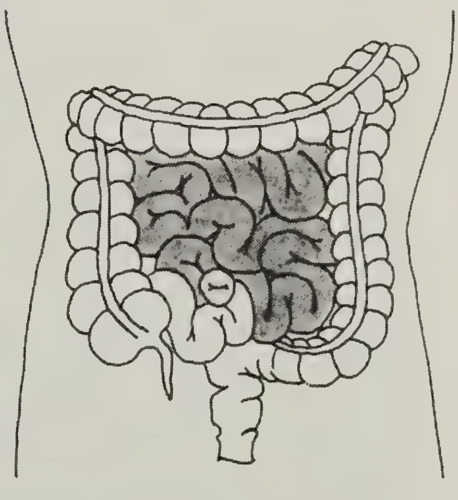
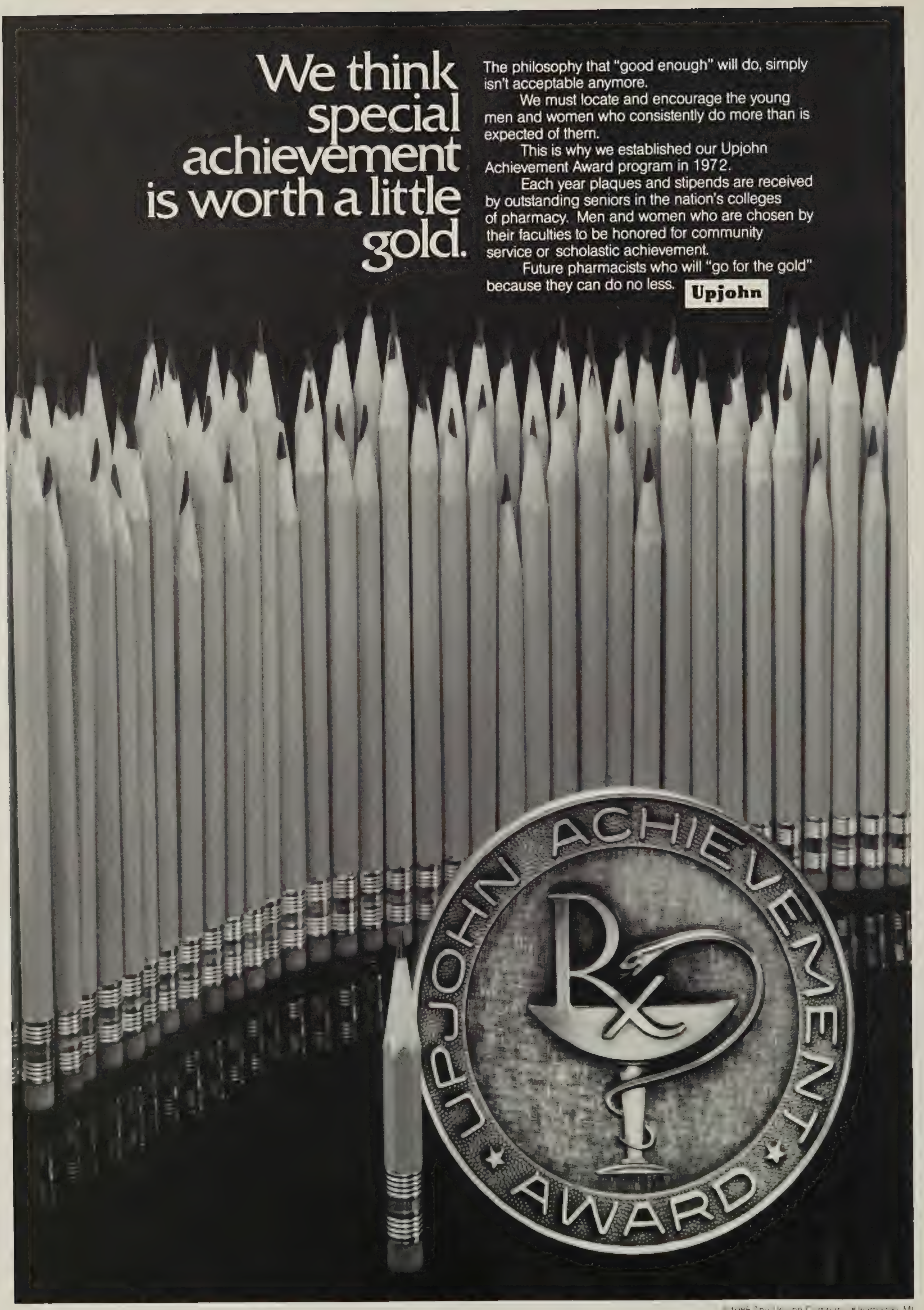


Figure 3. Ileostomy



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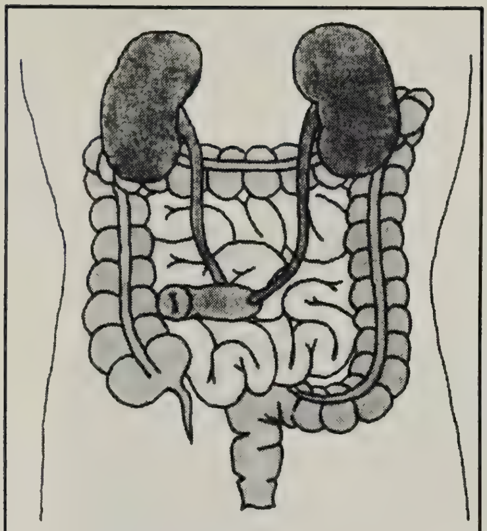


Figure 4. Ileal conduit

ideal because they help prevent an imbalance and also supply additional glucose.

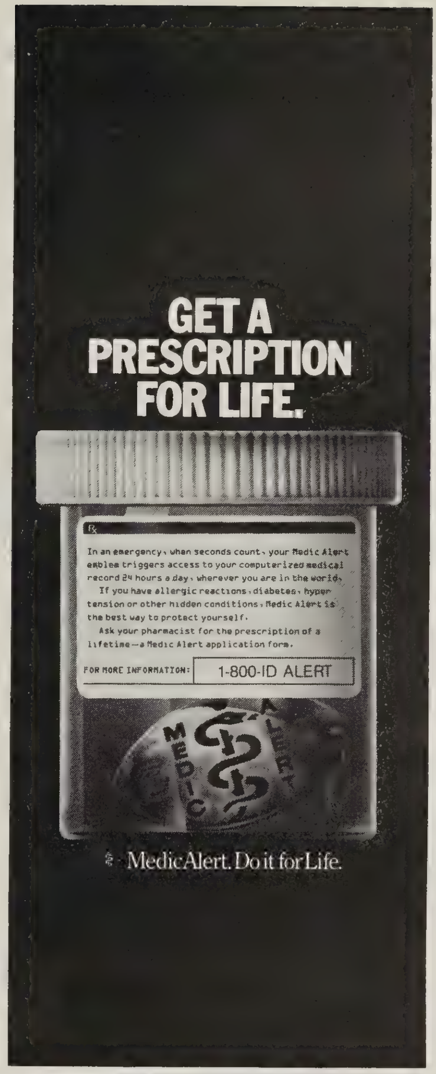
Ileal Conduit

This procedure is also referred to as an ileal loop, ileal bladder, or Bricker's Loop after the surgeon who described it (Figure 4). A 6- to 8-inch piece of ileum is removed and the ileum is rejoined to maintain normal function. The resected piece is then closed at one end, and the open end is brought through the abdominal wall to form a stoma. The two ureters are implanted into the closed end of the piece of ileum, and this then serves as the conduit for urine.

Although the ileal conduit serves as a collection duct for urine, it does not possess the elastic properties of the bladder, nor is there voluntary flow control. A few drops of urine will be excreted every 10 to 20 seconds. Since drainage is continuous, a light-weight, self-adhering, leakproof appliance is best.

Ileal conduit surgery is performed on patients with cancer of the urinary bladder, children with birth defects of the urinary tract, or incontinent patients with conditions such as multiple sclerosis, paraplegia, nonfunctioning bladder, or chronic urinary tract infections.

The topic of ostomies and ostomates will continue next month. It begins with a discussion of the special care an ostomate must take to assure a near-normal lifestyle. Various types of appliances and auxiliary products are also discussed, and advice for their correct use is presented.



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LETTERS

To Whom It May Concern:

This is a letter of accomadation for a very special pharmacist, Mr. James Sand.

My wife was suffering from bone cancer for nine months. During that time I had numerous occasions to purchase medicine from Mr. Sand's Mt. Airy Pharmacy. The complete professional attitude and quick response to our much needed prescriptions were always there. Mr. Sand did much, just to sight a few:

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6. Calling around to other pharmacies, if he was out of a needed prescription
7. Making special trips to his other pharmacy to obtain necessary medicines
8. Giving me his home phone number in case of an emergency during non-working hours

This gentleman is a *real pharmacist*. I can't say enough for Mr. Sand's assistance. I will always be indebted for his help and kindness.

Sincerely,
Jim White

Isadore Gresser

Maryland Pharmaceutical Association regrets the passing of Isadore (Izzy) Gresser on May 22, 1987. Izzy graduated from the University of Maryland School of Pharmacy in 1930. During his 43 years as a practicing pharmacist, Izzy worked for Stadium Pharmacy and Manheimers. He was a compassionate and professional pharmacist and he will be remembered fondly by his colleagues and patients.

New Column

The Pharmacist and Hospice

XII
IX
III
VI

IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

"The view commonly held by many Americans—that patients go to a hospice to die—is a myth" says Arthur G. Lipman, Pharm.D. "The hospice concept is not just one of providing appropriate medical and psychological support so that the patient can remain at home and hopefully die at home. The purpose is . . . for symptom control . . . and once the symptoms are controlled, the patient goes on living, instead of going on dying."

MANAGING CHRONIC PAIN IN THE TERMINALLY ILL

In terminal cancer, pain is a chronic problem. Unfortunately, patients who require narcotic analgesics to relieve their pain may not find them easily obtainable. A recent study in New York city cites that 29% of the 110 pharmacies surveyed carried no Schedule II narcotics, and only 54% stocked anything stronger than oxycodone combination products. While this may not be the case in other states, the results of this study indicate problems in locating pharmacies willing to carry the Schedule II drugs needed to relieve pain associated with cancer.

Morphine is one of the narcotics currently being used to manage severe pain. The optimal analgesic dose is considered to be 10 mg/70 kg of body weight, although larger doses are often used in the treatment of cancer pain. It is important to remember that the larger doses may be accompanied by an increase in the incidence of side effects.

Generally, oral administration of narcotic analgesics are preferred, as this gives the patient more independence than parenteral administration. Oral narcotics provide significant analgesia in most patients. Side effects associated with these drugs are primarily CNS effects such as sedation, confusion or agitation, hallucinations, nausea and vomiting, constipation and respiratory depression. Concomitant administration of other drugs may partially alleviate some of these adverse effects and should be used when necessary.

Brompton's Mixture, also referred to as Brompton's Cocktail or Brompton's Solution, originally was a combination of a narcotic and a stimulant in a hydroalcoholic vehicle. The original formulation which was used in England contained heroin; however, morphine was substituted when the formulation came into use in the United States. The stimulant (cocaine or dextroamphetamine) was used theroetically to counteract the side effects and potentiate analgesia. Phenothiazines were added to tranquilize, alleviate nausea and to potentiate analgesia. Alcohol may alter the patient's mood, but more frequently causes an increase in CNS side effects.

Presently there are many variations of the original Brompton's Cocktail being prescribed. Some physicians may prescribe a simple morphine solution, while still maintaining the name of Brompton's. Methadone solution is also sometimes used as a single agent. Recent studies suggest that single agent solutions are as effective as the combinations in relieving pain. In addition, titration is simpler since there are no other drugs to take into consideration when adjusting the dose.

There are some general principles that should be followed for pain management in the terminally ill patient. First, relief of pain is the primary goal. Sufficient doses of the analgesic should be given as frequently as needed to relieve pain. The dose will depend on many factors, including prior therapy, severity of pain, age, renal/hepatic function and concurrent drug therapy. Caution is particularly needed in the elderly. In general, smaller doses should be used initially, titrating to response.

Second, the concern of addiction should not be an issue. The patient will become physically dependent; however, the patient, family and health professionals should be reassured that the patient is not a "drug addict". Pain management should not be compromised because of these fears. Should the patient no longer need narcotics for pain control, the dose can be gradually tapered.

Third, avoid the use of additional drugs which potentiate the CNS depression or cardiovascular effects of narcotics. This is frequently a difficult task, as many of the drugs (antiemetics, sedative-hypnotics, anxiolytics) used concurrently in the terminally ill may have similar side effects.

Finally, in addition to drug modalities, the terminally ill patient requires strong psychosocial support. This support should come from family members, as well as the health professionals working with the patient.

It is important to remember that the patient may not always desire to be totally pain-free, sometimes preferring to have some pain in order to minimize confusion or other adverse effects. Health professionals should respect the decision of the patient in these instances.

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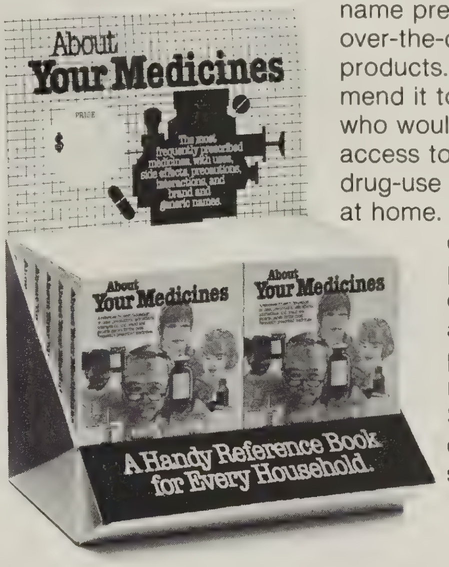
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MPhA Continues A New Member Service and Journal Feature

The patient education aid on the right is part of a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, MD. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

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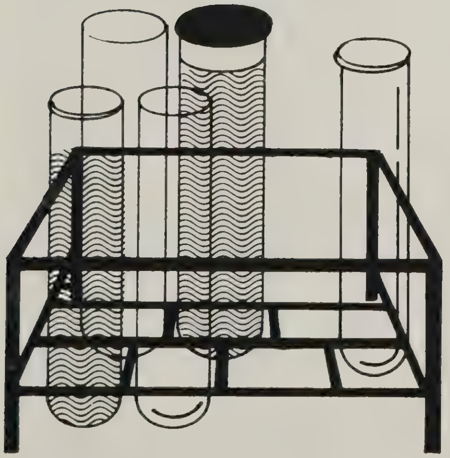
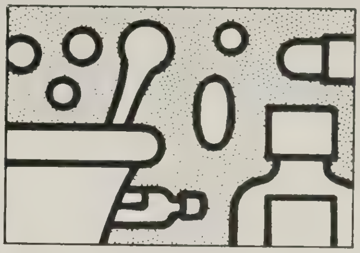


Things You Should Know FOR YOUR GOOD HEALTH



August is Good Nutrition Month

Vitamins and minerals, along with proteins, fats, carbohydrates and water, are essential for a healthy functioning body. If your diet consists of a good selection of foods, it can supply the vitamins and minerals most adults need.

But, how many of us are aware of the nutritional value of each meal that we consume? Often fast-foods, snacks, dieting, poor appetite and stress can interfere with satisfying your nutritional needs. No matter what the cause, deficiencies may involve not only one vitamin or mineral, but several. In such cases, a multivitamin and mineral replacement is essential. If you think you need a vitamin or mineral supplement, discuss your eating habits and other related problems with your doctor or pharmacist.

Common vitamins and minerals, their food source, and their use in the body are described below.

Vitamin A is found in eggs, fish, milk, butter, yellow and green vegetables. Helps promote normal growth and maintain healthy skin, eyes, teeth and gums.

Vitamin B-1 (Thiamine) is found in beans, liver, nuts, pork, poultry, milk, fish, eggs, yeast, potatoes and broccoli. Essential for a healthy nervous system. Encourages normal appetite and digestion. Prevents fatigue and irritability.

Vitamin B-2 (Riboflavin) is found in spinach, broccoli, peas, milk, cheese, liver and meat. Helps cells use oxygen. Keeps skin, tongue and lips normal. Prevents scaly, greasy skin around the mouth and nose.

Vitamin B-6 (Pyridoxine) is found in lentils, nuts, potatoes, avocados, corn oil, liver and cereals. Necessary for a well functioning nervous system. Important in the proper metabolism of proteins and fats. Helps maintain healthy skin and healthy red blood cell formation.

Vitamin B-12 (Cyanocobalamin) is found in liver, brewer's yeast and wheat germ. Deficiency can appear in strict vegetarians. Helps protect against certain forms of anemia and helps stimulate appetite. Important in cell production and increases red blood cell formation.

Vitamin C (Ascorbic Acid) is found in citrus fruits, strawberries, pineapple, tomatoes, cauliflower, cantaloupe, cabbage, broccoli, potatoes and green peppers. Essential for healthy bones, teeth, cartilage, blood vessels and connective tissues, and other body functions.

Vitamin D (Ergocalciferol) is found in fish liver oils, eggs, and sunlight. Many foods are fortified with Vitamin D, particularly milk products and cereals. Promotes the proper use of calcium and phosphorus necessary for building strong bones and teeth.

Vitamin E is found in vegetable oils, eggs and liver. Necessary for development and function of blood, muscle cells and other tissues. Increased use of polyunsaturated fats increases need for Vitamin E.

Calcium is found in milk, cheese, green leafy vegetables, string beans, eggs, salmon and dates. Builds strong bones and teeth. Promotes a healthy nervous system and skin. Plays an important role in muscle contraction, transmission of nerve stimuli and clotting of blood.

Iron is found in liver, meats, vegetable greens, asparagus, peas, apricots, dried fruits, eggs and shell fish. Used to protect healthy red blood cells and in oxygen transportation to cells.

Zinc is found in vegetables. Essential for utilization of carbohydrates and protein. Aids in respiration and wound healing, especially following surgery and trauma.

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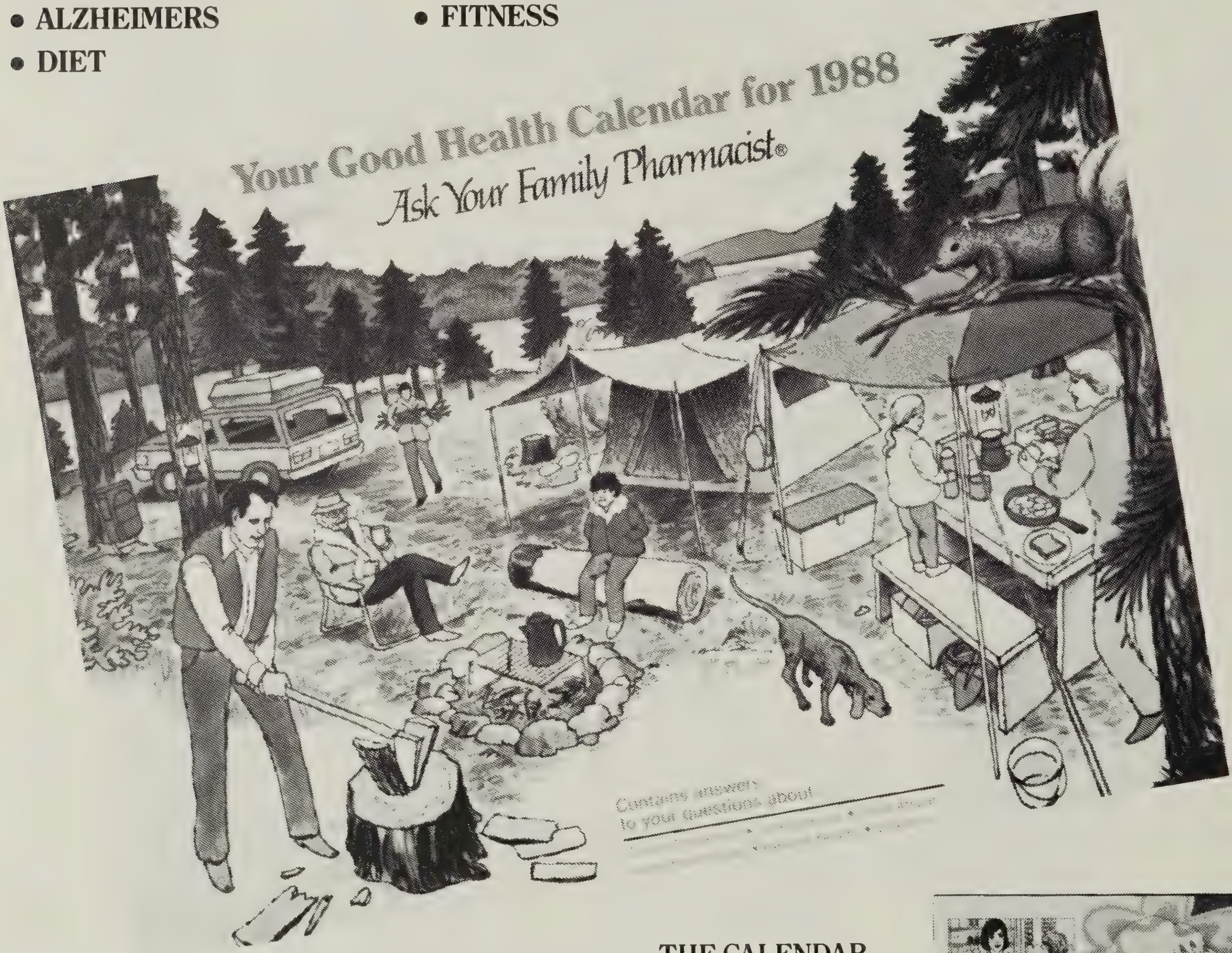
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009	Antidiarrheals (Oral)	
010	Antidyskinetics (Oral)	
011	Antifungals (Topical)	
012	Antihistamines (Oral)	
013	Antihistamines and Decongestants (Oral)	
014	Benzodiazepines (Oral)	
015	Beta-blockers (Ophthalmic)	
016	Beta-blockers (Oral)	
017	Calcium Channel Blockers (Oral)	
018	Cephalosporins (Oral)	
019	Cimetidine/Ranitidine (Oral)	
020	Digitalis Medicines (Oral)	
021	Dipyridamole (Oral)	
022	Erythromycins (Oral)	
023	General Information About the Use of Medicines	
024	Hydantoins (Oral)	
025	Indomethacin (Oral)	
026	Insulin (Injection)	
027	Iron Supplements (Oral)	
028	Loop Diuretics (Oral)	
029	Methyldopa (Oral)	
030	Narcotic Analgesics and Acetaminophen (Oral)	
031	Narcotic Analgesics and Aspirin (Oral)	
032	Nitrates (Oral)	
033	Nitrates (Sublingual)	
034	Nitroglycerin (Topical)	
035	Nonsteroidal Antiinflammatories (Oral)	
036	Ophthalmic (Eye) Drops and Ointments	
037	Penicillins (Oral)	
038	Phenothiazines (Oral)	
039	Potassium-sparing Diuretics and Hydrochlorothiazide (Oral)	
040	Potassium Supplements (Oral)	
041	Prazosin (Oral)	
042	Skeletal Muscle Relaxants (Oral)	
043	Sulfonamides (Oral)	
044	Tetracyclines (Oral)	
045	Thiazide Diuretics (Oral)	
046	Thyroid Hormones (Oral)	
047	Tricyclic Antidepressants (Oral)	
048	Xanthine Bronchodilators (Oral)	

PHARMACIST CONTROL OVER OTC MERCHANDISING

Donna Eby
Mary Beth Friedel
Ronni Robinson
Dr. Alan McKay

The involvement of community pharmacists in patient counseling and monitoring can be singled out as a major patient care activity of the pharmacy profession, and has long been a source of professional pride. In recent years several factors have combined to focus increased attention on this role. The recent switch of several legend drugs to OTC status has had a major impact on the potential for patient counseling by the pharmacist. The consumer has become increasingly aware of the importance of information concerning the use of drugs of all kinds, especially Over-the-Counter Medications (OTC's). Some critics of the Rx to OTC product movement have called for the creation of a third, intermediate, class of drug products which would be subject to pharmacist control. Pharmacists, supported by their professional organizations, have argued for an expanded role in product selection and, in the case of the state of Florida, limited prescribing authorization. The result has been heightened interest in the degree to which pharmacists are capable and willing to become involved in the supervision and possible control over the use of certain classes of drug products.

This study examines the issue of pharmacist involvement in the selection of existing non-prescription products, including products that have recently moved from prescription to OTC status and products that, by various definitions, may be viewed as controversial. Our purpose was to determine whether pharmacists who have authority over the merchandising of OTC products are currently making any effort to "control" certain categories of over-the-counter drug products by stocking them behind or on the prescription counter, giving the pharmacist the opportunity to provide counseling to customers purchasing these products.

HYPOTHESIS

1) Recent Rx to OTC switches and items which may require some patient counseling for safe and appropriate use will be placed behind the prescription counter in a higher percentage of pharmacies where a pharmacist determines the placement of OTC products within the store than in those pharmacies where a nonpharmacist supervisor determines OTC product placement.
2) Items with questionable efficacy will fall into the "not carried" category in more of the pharmacies where a pharmacist decides which OTC items will be carried than in those pharmacies where a non-pharmacist supervisor decides which OTC items will be carried.
3) Because of recent controversy over the abuse of Ipecac syrup by bulimics, some pharmacists who have control over placement of OTC's will opt to keep this product behind the counter.

METHODOLOGY

Our preliminary study utilized a two page, eight-item mail survey without follow-up to 110 professional practice preceptors within the University of Maryland's professional experience program. Seventy-seven responses were received by the cutoff date, reflecting a return rate of 63.6%. Since the subjects were not randomly selected, the answers reflect a degree of consistency in standards of practice associated with the position of a preceptor. The results of this pilot study were used to make revisions as to wording of the survey questions and choice of products.

The revised two page eight-item mail survey was then sent to a random sample of 549 pharmacists drawn from the State Board of Pharmacy's current list of licensed practitioners in Maryland. A follow-up mailing took place three weeks after the initial mailing. All responses were kept confidential except for follow-up purposes. Responses were numerically coded to allow for ease of analysis by computer.

Questions were divided into three basic areas:

1) demographics: pharmacist characteristics (age/sex), practice type (independent/chain), and clientele;
2) pharmacist involvement in product control, selection or merchandising; and
3) locations of actual products in relation to the prescription area.

"Degree of control" was defined as the proximity of a specific product to the prescription counter or as the availability of a certain product to the consumer without pharmacist's availability for counseling; for example, the closer a product was to the pharmacist, the more potential supervision he could offer over the purchase or use of the product.

CHARACTERISTICS OF THE SURVEY GROUP

196 of the 549 surveys mailed were returned, giving an overall response rate of 35.7%. Of the 196 surveys returned, 51 were from institutional pharmacists or other non-retail pharmacists, and were, therefore, unusable. Two of the 196 were duplicates sent back in the

second mailing by pharmacists who had already responded to the first mailing.

Of the 143 usable questionnaires returned, 74 were from independents, and 69 were from chain pharmacists. The mean age of the group was 39 for the chain pharmacists, and 46 for the independents. The chain group was 72% male, and the independent group was 78% male.

A total of 38% of the respondents indicated that a pharmacist had authority over the merchandising of OTC products. Twenty-four percent indicated that a non-pharmacist supervisor had this authority. The remaining 38% indicated that neither a pharmacist nor a non-pharmacist supervisor had complete authority over merchandising of OTC products. Ninety-two percent of the stores where a pharmacist controlled the placement of OTCs were independent pharmacies, while 85% of the stores where a non-pharmacist supervisor controlled the placement of OTCs were chain pharmacies.

DISCUSSION OF RESULTS

In general, a slightly greater difference was apparent between chain and independent pharmacies than between pharmacists who do or do not have merchandising authority with respect to where they stocked the products we listed.

Recent Switches: If pharmacists with merchandising authority were using their authority to exert some kind of control over any class of drugs, recent switches from Rx to OTC status would seem a likely category for them to control. In the pilot study, the overwhelming majority of respondents, both chain and independent, and both with and without merchandising authority stock the recently switched items we listed in their regular inventory (either within 10 ft or beyond 10 ft of the prescription counter). However, in the follow-up study using a larger sampling of pharmacists from across the state, a small, but significant portion (7%) of the pharmacists who had authority over the merchandising of OTCs indicated that products in this category were kept behind the Rx counter. Conversely, none of the stores where a non-pharmacist supervisor controlled the merchandising of OTCs elected to keep any of these products behind the counter.

Controversial Products: The questionnaire included a group of products which we felt might, for some reason, be considered controversial in terms of either safety or efficacy. If pharmacists were indeed exerting their professional influence over certain types of OTC products, some pharmacists might be expected not to carry certain of these items in their pharmacy, or to keep certain items behind the prescription counter, where the pharmacist would presumably have more opportunity to advise patients in the proper use of these products. A full 57% of stores with a pharmacist in control of OTC purchasing elected not to carry the nonprescription diuretic product we listed, while only 3% of the supervisor-controlled purchasing group did not carry the product. Boric acid was kept only behind the prescription counter in 30% of pharmacies with a pharmacist in control of merchandising, and in only 12% of pharmacies with a non-pharmacist in control. The topical aspirin product we listed was carried in regular inventory (either within 10 feet or beyond 10 feet of the prescription counter) by 100% of the pharmacies with a non-pharmacist in charge of merchandising, while a total of 13% of the pharmacists in charge of merchandising elected to keep this product behind the counter, or not to carry it at all. The caffeine product we listed was kept behind the prescription counter or not carried at all by 28% of pharmacists in charge of merchandising, while none of the stores with a non-pharmacist in charge of merchandising chose to keep this product behind the counter or not to carry the product.

Laxatives: Several products in the laxative category are not recommended for regular or long term use, or may require some special instructions to the patient regarding their safe and effective use. Significant differences were found between pharmacies with a pharmacist in charge of merchandising and those with a non-pharmacist in charge of merchandising with respect to the placement of products in this category, especially Magnesium Citrate, and Bisacodyl. A total of 19% of pharmacists in charge of merchandising elected to keep these products behind the counter, or not to carry them, while none of the stores with a non-pharmacist in charge of merchandising chose either to keep these products behind the counter, or not to carry them.

Diet Pills: In the pilot study, a substantial percentage of our respondents did not carry most of the phenylpropanolamine-containing diet products we listed: 22% for the market leader in this category, and an average of 45% for the less well-known brands. The percentage of independent pharmacists who chose not to carry these products was about twice that of the chains. In the follow-up study, only an average of 12% of the respondents did not carry the products we listed. It is interesting to note, however, that all of the pharmacies where a non-pharmacist supervisor controlled the purchasing and merchandising of OTC products, and also all of the chains chose to carry these products.

Contraceptives: Representatives of some groups concerned with the problem of teenage pregnancy have noted that pharmacies may be contributing to this problem by keeping contraceptive products behind the prescription counter where the patient must ask for them. Only 10% of the respondents overall stock any of these items behind the counter. The largest group of respondents stocked contraceptive products in regular inventory within 10 feet of the prescription counter. However, a full 20% of pharmacists in control of OTC merchandising stocked condoms behind the prescription counter, while only 3% of the stores where a non-pharmacist supervisor determines placement of OTCs elected to keep these products behind the counter. Perhaps even more significant was that fact that fully

Control of OTC Products by Pharmacist Merchandising Authority

a = % of Pharmacists with merchandising authority
b = % of pharmacists with no merchandising authority
c = % overall

Product	Displayed in regular inventory beyond 10% ft			Regular inventory within 10% ft			ON Counter			Behind RX Counter			ITEM NOT CARRIED		
	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
Recent Switches:															
1. Benadryl	31	68	52	59	29	41	0	0	3	7	0	4	0	0	0
2. Drixoral	31	68	51	61	29	43	0	3	1	7	0	5	0	0	0
3. Advil	30	65	48	61	32	46	2	3	3	7	0	4	0	0	0
4. HC Cream	30	41	45	61	56	50	2	3	1	3	0	3	0	0	0
Questionable Efficacy:															
5. Benadryl Cr	31	44	45	52	53	44	2	0	1	7	3	5	7	0	4
6. Aspercreme	39	59	52	46	41	41	2	0	1	11	0	6	2	0	1
7. Vick's salve	37	71	54	57	29	43	0	0	0	6	0	4	0	0	0
8. Boric Acid	24	44	38	44	38	38	2	0	1	30	12	20	0	6	3
9. Diurex	13	44	34	19	53	30	4	0	1	6	0	4	57	3	31
Sleep Aids:															
10. Sominex	30	59	45	43	38	37	6	3	4	13	0	6	9	0	8
Caffeine:															
11. No-Doz	26	59	44	43	38	37	4	3	4	17	0	7	11	0	8
"Natural" Remedies:															
12. Gensing	15	7	20	31	41	35	0	3	1	4	0	1	50	27	42
13. Tryptophan	20	35	29	57	53	55	2	6	3	1	0	1	17	6	12
14. Vit E Cream	30	65	44	52	26	43	4	0	1	4	0	1	11	9	10
Laxatives:															
15. Colace	35	68	51	48	26	39	4	0	1	13	3	8	0	3	1
16. Dulcolax	31	71	51	48	29	40	2	0	1	17	0	8	2	0	1
17. Mag. Cit.	41	74	56	41	26	37	0	0	0	15	0	6	4	0	1
18. Haleys MO	44	76	58	35	21	31	0	0	0	9	0	4	11	3	8
19. Castor Oil	28	68	47	48	26	40	0	0	0	24	6	13	0	0	0
Diet Pills:															
20. Fibretrim	33	47	45	48	50	45	4	0	1	7	0	4	7	3	6
21. Dexetrim	30	44	43	41	56	41	6	0	2	7	0	4	17	0	10
22. Accutrim	28	44	43	37	56	38	6	0	2	7	0	4	22	0	13
Contraceptives:															
23. Condoms	20	29	24	46	56	51	2	12	8	20	3	10	9	0	6
24. Foams, gels	41	50	46	41	47	44	0	3	1	13	0	5	6	0	4
25. Sponge	41	50	45	37	44	41	2	3	2	9	0	4	11	0	8
Test Kits:															
26. Ovulation detect. kit	24	21	26	50	53	46	0	12	5	19	15	16	7	0	6
27. Preg. Tests	22	29	29	57	56	52	4	12	6	19	3	10	0	0	2
28. **Ipecac**	4	9	10	39	15	26	9	6	6	48	71	57	0	0	0

38% of our respondents shelved condoms in a completely separate place from the other contraceptive products we listed (foams, gels, and sponge). This finding supports the concern that some confusion on the part of the consumer may result from the placement of contraceptive foams and gels in the feminine hygiene section alongside similarly packaged non-contraceptive products.

Ipecac Syrup: All of the respondents carry Ipecac syrup in their pharmacies, but a significant difference exists in the placement of this product. The product was placed behind the prescription counter in 48%, and in regular inventory in 43% of the stores with a pharmacist in control of merchandising. The product was placed behind the counter in a full 71% and in regular inventory in only 24% of the stores with a non-pharmacist in control of merchandising. This finding may reflect the controversy in pharmacy literature regarding control of this product. Poison centers have stressed that the importance of keeping the product readily available to the public outweighs the problems associated with its misuse. One might expect pharmacists to be more aware of both sides of the controversy, while non-pharmacists are likely to be aware only of the highly publicized problems associated with abuse of the product.

Control of OTC Products Chain versus Independent Pharmacies

a = % of Independent Pharmacists
b = % of Chain Pharmacists
c = % overall

Product	Displayed in regular inventory beyond 10% ft			Regular inventory within 10% ft			ON Counter			Behind RX Counter			ITEM NOT CARRIED		
	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
Recent Switches:															
1. Benadryl	34	71	54	54	28	41	5	0	3	7	0	3	0	0	0
2. Drixoral	32	71	51	57	29	43	1	0	1	9	0	7	0	0	0
3. Advil	26	71	48	61	29	45	5	0	3	8	0	4	0	0	0
4. HC Cream	31	59	45	31	41	50	3	0	1	5	0	3	1	0	0
Questionable Efficacy:															
5. Benadryl crm.	34	58	45	51	36	44	3	0	1	5	4	5	7	1	4
6. Aspercreme	38	67	52	49	33	41	1	0	1	11	0	6	1	0	1
7. Vapo-Rub	35	74	54	58	26	43	0	0	0	7	0	4	0	0	0
8. Boric Acid	30	49	38	43	32	38	1	0	1	23	17	20	3	3	3
9. Diurex	18	51	34	19	42	30	3	0	1	7	0	4	53	7	31
Sleep Aids:															
10. Sominex	26	67	45	42	32	37	7	1	4	11	0	6	15	0	8
Caffeine:															
11. No-Doz	22	68	44	40	30	37	5	1	4	14	0	7	16	0	8
"Natural" Remedies:															
12. Gensing	12	29	20	30	41	35	0	3	1	3	0	1	55	28	42
13. Tryptophan	20	38	29	59	51	55	1	4	3	3	0	1	16	7	12
14. Vit E Cream	27	62	44	55	29	43	3	0	1	3	0	1	12	9	10
Laxatives:															
15. Colace	30	70		53	25		3	0		11	4		0	1	
16. Dulcolax	30	74	51	53	26	39	1	0	1	15	0	8	1	0	1
17. Mag. Citrate	41	72	56	46	28	37	0	0	0	11	0	6	3	0	1
18. Haleys M.O.	45	72	58	39	22	31	0	0	0	7	0	4	9	8	6
19. Castor Oil	31	64	47	51	28	40	0	0	0	18	7	3	0	0	0
Diet Pills:															
20. Fibretrim	31	59	45	50	39	45	3	0	1	7	0	4	9	1	6
21. Dexetrim	31	57	43	38	43	41	4	0	2	7	0	4	20	0	10
22. Accutrim	30	57	43	34	43	38	4	0	2	7	0	4	26	0	13
Contraceptives:															
23. Condoms	24	23	24	40	71	51	18	13	8	19	1	10	12	0	6
24. Foams, gels	45	48	46	41	48	44	0	3	1	8	1	5	7	0	4
25. Sponge	43	48	45	35	46	41	1	3	2	5	1	4	14	0	7
Test Kits:															
26. Ovulation detect. kit	27	25	26	46	49	48	1	9	5	16	16	16	9	1	6
27. Preg. Tests	26	32	29	50	55	52	4	9	6	16	4	10	4	0	2
28. **Ipecac**	11	10	10	39	12	26	8	4	6	42	74	57	0	0	0

CONCLUSION

Because of the high percentage of pharmacists in control of merchandising in independent community pharmacies, and the high percentage of non-pharmacists in control of the merchandising in chain pharmacies, it is not possible to determine whether the differences found were due to the pharmacists influence in the merchandising of OTC products, or simply due to basic differences between the chain and independent philosophies of merchandising. Our results indicate that pharmacists, for the most part, are not attempting to control recently switched products through placement of those products on or near the prescription counter. Pharmacists do, however, appear to exert their influence in the merchandising of certain other types of products: those which have questionable safety or efficacy, and those products where proper use may require some additional instructions to the patient.

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Writing Letters

Commentary

by Jim Dickinson

Pharmacists who write letters get their way, and if only more would do it, more would be done for the profession.

After reporting the salutary effects of your letters to HHS Secretary Don Newman on the question of mandatory Medicaid discounts, I've had other evidence on the power of pharmacy's pens.

"I had almost given up writing any more letters," writes Sutter Creek (Calif.) pharmacist Paul Wesseler, "but I wrote to Don Newman at your suggestion. Thanks for reporting the results. Now I am more ready to fight the MD dispensing issue . . ."

So, apparently, are many more pharmacists. Capitol Hill saw the largest outpouring of grassroots pharmacy energy anyone can remember, after the National Association of Retail Druggists activated a 60,000-piece "legislative alert" mailing on the dispensing physicians issue in April.

The heat was so intense that one congressman reportedly assigned a staffer fulltime to fielding pharmacists' telephone calls.

NARD's strategy was devastatingly simple, if expensive. It followed up its "alert" mailing (which went to non-members as well as to NARD members) with two Western Union Mailgram alerts, one of which triggered state association and local grassroots alert systems on the eve of critical votes by House committees.

Needless to say, both votes went pharmacy's way, largely overcoming American Medical Association opposition to federal restrictions on physician prerogatives. The AMA had earlier joined with NARD and the National Association of Chain Drug Stores in a statement opposing physician dispensing for profit (a position compatible with its traditional posture down the years), but it insists that its members are too honorable to need a law—especially a federal law.

Now, the united forces of pharmacy face some exceedingly dishonest tactics by the drug repackagers who exploit physicians' economic misfortunes in the doctor glut. As these hucksters face their fate, they're turning nasty, openly recommending the elimination of the retail pharmacy marketing level from the drug distribution system.

And they're aiding AMA efforts to defeat federal legislation on the ground that it's a state function to police the practice of medicine. The repackagers would rather fight 50 different fights, with help from the politically extremist and anti-pharmacy Federal Trade Commission in each fight, than lose it all in one Washington fight where the FTC is out of favor.

But it's the awesome power of the pharmacist's pen that will win or lose this fight. Pharmacists have seldom coalesced on an issue as they're coalescing on this one.

Write your Congressman and your two Senators now. This much you can do!

Showing the Way

Drug companies have been everyone's favorite villains for so long now, it comes as a shock to see the industry any other way.

But there in the middle of the Gary Hart fiasco, the Irangate hearings, the PTL scandal, insider trading on Wall Street, and a seemingly endless list of other national shames, everyone's favorite villain (the PMA) took the high road in May.

Hard on the heels of a severe beating it received a few weeks earlier in Congress over drug price increases, the PMA on May 4 went on record as being opposed to sales of investigational drugs.

The very companies that had just been lambasted for "greed on a massive scale" by House health chairman Henry A. Waxman (D-Cal.), turned their backs on the potentially enormous profits that might be legally made on unapproved drugs such as numerous AIDS and cancer treatments still under development.

The PMA's position puts its members' own *long-term* interests ahead of their short-term interests, setting the industry apart and high above the likes of Gary Hart, Irangate manipulators, inside-traders *et al.*

The investigational-drugs-for-sale issue, advanced to its great discredit by the Food and Drug Administration as a quick fix for bringing AIDS drugs to the terminally ill before they're tested properly, could profit companies in the short term, but cost them dearly in the long-term, PMA realized.

Primarily, if you can make a quick profit without doing expensive, and potentially self-defeating research, the system will eventually be skewed away from the long, hard grind of finding truly valuable therapies.

PMA recognized, at least in this instance, that our society already has too much of a tendency to live for today and to let tomorrow take care of itself.

As with physician dispensing also, any time a vested-interest group (whether retail pharmacy or drug innovators) puts the long-term view ahead of the short-term view, chances are the public interest with be advanced.

In both of our examples above, surely this is the case.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

NEW TECHNOLOGIES

by Kathleen Gondek, Pharmacy Student

"Health care, despite recent advances in technology is still quite labor intensive; productivity growth is low, or even negative by some measures (1)." One method of reducing expenses is the implementation of new technologies, however, care must be taken not to automate an inefficient operation as the result will be a highly inefficient automated operation. This conclusion was realized in many offices that purchased computers and today have many idling. An often forgotten aspect of a new technology is the cost of education and training. These costs should be incorporated to give a more realistic picture of the actual cost incurred in changing the current system.

Bar codes have been implemented in various areas within the health care industry. The Health Care Industry Bar Code Council (HIBCC) was established in 1983 and has developed standards and guidelines for the use of bar coding in hospital applications. Most applications of bar coding in hospitals have been in materials management. Significant cost savings were realized at The Children's Memorial Hospital in Chicago, Illinois where bar coding allowed for more effective billing of supplies used by patients and a more accurate inventory (2). Health care facilities in general benefit through improved tracking within their computer systems eliminating manual data entry resulting in more accurate and timely handling of patient information, services, charges and more efficient inventory control (3).

Adding bar codes does add to the expense of production (4). Placement of bar codes on the outside of bulk packages is less expensive than smaller packages. Therefore, unit dose packages represent a problem not only in cost but also the physical size of the bar codes is larger than most of the unit dose packaging. The cost could be roughly two cents per unit dose package (4). There now exists invisible bar codes that can be placed on units dose packages more readily than the well known black lines. In addition to this expense some type of computer is necessary as is a device to decode the bar codes.

The automatic dispensing system the ATC is a computer driven, electromechanical device that can be interfaced with a pharmacy management system (5). There are two major electromechanical components in the system: the 212 medication-specific storage canisters and a printing-packaging-sequencing mechanism which ultimately delivers a patient-specific unit dose packaged medication.

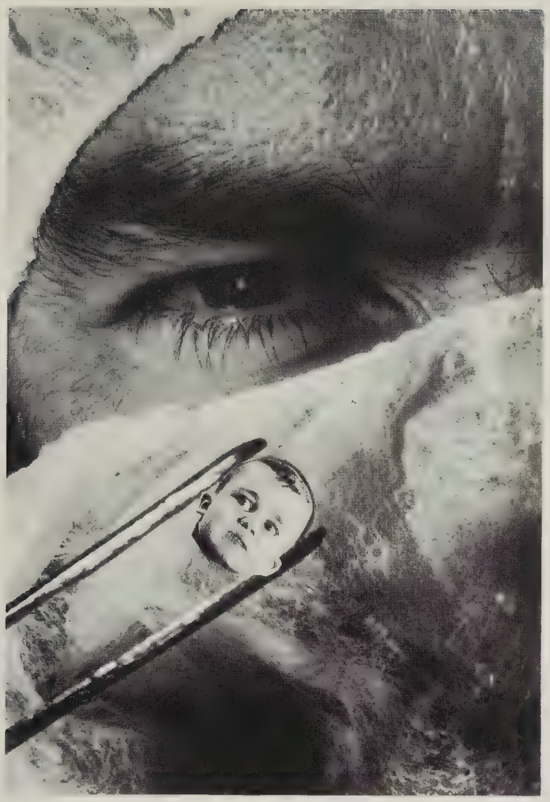
The ATC system can function as a stand-alone system in a non-computerized pharmacy or it can be interfaced with the pharmacy's current system. The medications will be dispensed in a sequence that will facilitate the cart filling and medication administration process. The software will also allow the dispensing sequence to be interrupted so that stat orders may be dispensed. The packaging speed is approximately twenty-five packs per minute with four lines of printing.

There are several levels of security built into the system to minimize the possibility of error. First only personnel authorized by a code number will be able to access the file which will determine which drugs will be dispensed for which patients. Each canister is calibrated to the dimensions of a specific drug, to minimize error from incorrect filling of a canister. Each canister is mechanically keyed to a certain slot on the machine to eliminate the possibility of incorrect placement of the canisters. Each canister and each slot will be labeled with medication identification.

The final product of the ATC is a unit dose oral solid contained in a package labeled with medication identification plus patient identification and time of administration. The proposed advantages to this system are that it will reduce the labor required in the cart filling process and allow the purchase of more drug in bulk containers as opposed to unit dose packages which are more expensive.

The Automix Plus with computer software will aid in the compounding of parenteral nutrition solutions (6). By interacting with the automix compounder the software facilitates control of compounding by a personal computer system. The program functions include entering patient information and prescription data, performing calculations associated with compounding, transmitting data to the Automix Plus and generation of reports.

The program is flexible, allowing the input of ni-



trogen and dextrose to either be in grams, final concentrations of each component, solutions volumes or any combination of the aforementioned. The program can store 30 standard solutions, up to 25 additives can be selected, previous patient formulations can be recalled and upon entering such information, ingredient volumes are calculated from doses ordered and are printed out onto a worksheet. Solutions can be compounded individually or sorted into any four batches throughout the day. Labels can also be generated from this system. The approximate cost of the software is $2000. Record keeping represents the strength of the program.

Micromix with computer software will aid in the compounding of total parenteral nutrition. This program allows for the addition of electrolytes to the TPN base solution. It has an ability to measure from 0.1 to 100 ml and transfer up to ten additives. The Micromix is now in premarket trials. The expected cost of the Micromix is $40,000.

In addition to the computer drive technologies, innovations in drug delivery systems are being developed. Much of the research has been in the area of controlled release, which may be a consequence of not only the realization that controlled delivery prolongs the duration of drug delivery but also implies predictability and reproducibility in drug release kinetics (7). Today such products on the market exist but the new systems including the use of polymers as one of the major excipients and the area of programmable controlled delivery systems represent the hot topics in the industry.

An example of the use of polymers is a system with a collapsible drug compartment enclose inside a rigid, shape-retaining housing. A laminate comprised of an absorbent layer and layer swellable cross-linked polymer is placed between the drug compartment and the external housing (7). There are annular openings which facilitate absorption of gastrointestinal fluids. The absorption expands the laminate and generates hydrodynamic pressure this forces the drug laminate and generates hydrodynamic pressure. This forces the drug compartment to collapse, thereby delivering drug (liquid) through the opening. Many other drug delivery systems are currently being investigated such as tissue plasminogen activators, recombinant DNA, monoclonal antibodies, antivirals, immunologic agents and transdermal systems to name a few.

The cost of new technologies is staggering. The ATC by Travenol can be purchased for $100,000 to 300,000. The canisters can only be used for a drug of a specific manufacturer, like Baker cells. The canisters themselves are produced in Japan; replacement may take greater than one month. It will still be necessary for a technician to fill carts with the elimination of choosing the appropriate drug from a picking station.

The Automix Plus allows us to prepare TPNs in less time, with less inventory and with greater accuracy when compared to the conventional methods.

Bar coding has had its greatest success in materials management departments within the health care industry. The success in departments of pharmacy will rely on the pharmaceutical companies cooperation. It would be more cost effective if the bar coding was done by the companies rather than the individual departments of pharmacy. Pharmacists must continue their educational efforts in many of these new and developing areas.

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Giving the Consumer a Say

By Bruce R. Siecker, Ph.D., R.Ph., and Beverly A. Gilbert,
R.Ph., Galaxy Enterprises, P.O. Box 1242, Springfield, VA 22151.

With so many choices facing the consumer, it is very important that pharmacists know how they and their pharmacy rate with area shoppers.

People have many more choices today in deciding where to get their prescription needs, health and beauty aids, and the various sundries found in the typical community pharmacy. Grocery and mass merchandisers, together with mail-order, physician dispensing, and hospital out-patient services, are all competing for the same consumers. In such an environment, it is very important that pharmacists stress service by continually monitoring their clientele.

Consumers are increasingly segmenting themselves into narrower life-style bands. The saturday shopper in jeans may be the same one that wears a business suit during the week. What appears to the casual observer

* * *

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Sale prices	1	2	3	4	5
Overall value for money spent	1	2	3	4	5
Complaints handled satisfactorily	1	2	3	4	5
Return policy	1	2	3	4	5
Store hours	1	2	3	4	5
Store cleanliness	1	2	3	4	5
Parking area	1	2	3	4	5
Emergency prescription service	1	2	3	4	5
Delivery service	1	2	3	4	5
Overall rating of ABC Pharmacy	1	2	3	4	5
Compared to other stores	1	2	3	4	5

Comments: Please tell us what else—complaint? compliment? An outstanding employee?—you think we should know or improve.

Thank you very much. Simply fold this form in half and staple; then drop it in a mailbox. Postage paid by ABC Pharmacy.

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* * *

to be a neighborhood full of married couples may in reality be singles who are simply sharing housing expenses. Their needs and shopping behavior are often quite different than what might be expected. The challenge for today's pharmacy manager is to identify the nature of current and potential customers in some systematic way as a means of keeping the pharmacy in synch with its environment.

Trying to determine shopper reactions and needs in a busy pharmacy is not easy. Often shopers are too busy to talk or may feel reticent to express their real feelings directly. They may also need more time to think about their answers. Trying to ask their opinions in the store may disrupt normal service, which is counterproductive to the intended purpose.

If customer service is to be more than a buzzword, it makes sense to learn what customers really want by asking them in a systematic fashion. One way to accomplish this is to use a written, self-addressed, postage-paid questionnaire that shoppers would be asked to complete and mail back to the pharmacy. An effective way to position such a program is to give it a special name, e.g., "Rate Us", "It's Your Turn", or "You Tell Us". Employees should be told of the importance of the effort—"It is our way of learning what the customer really wants; a satisfied customer is easier to serve, which will make your job easier"—and be given suggested ways of presenting the program to shoppers —"Mrs. X, here is our new 'Rate Us' survey form. We really want to learn what you think of us and how we can do a better job for you. Won't you please take a few minutes to fill out the form, when you get home. Then just staple it closed and drop it in a mailbox. We'll even pay the postage. We read and discuss each card sent in and do our best to improve our service to you."

There are many questions that can be asked and different ways to set up such a questionnaire. Here is a sample that can be used as is or as the basis for developing your own. (The reverse side can be used for the return address and a message to the shopper.)

One employee should be given the responsibility—a good candidate is one with a history of problems in understanding why good service is so important in a community pharmacy (as a good object lesson)—of recording and compiling the results on a periodic basis. Customer feedback, honestly considered and acted on, is surely preferable to this simply going somewhere else. Survey results can be used effectively in staff meetings to improve every aspect of a pharmacy's operation, particularly employee attitudes.

In today's highly competitive world, pharmacy employees and managers need constant reminders that consumers have real choices. The best way to assure that they choose your pharmacy is to seek their views continually. If listening is followed by sincere action that maintains a truly market-driven pharmacy, the future of community pharmacy services will be much brighter.

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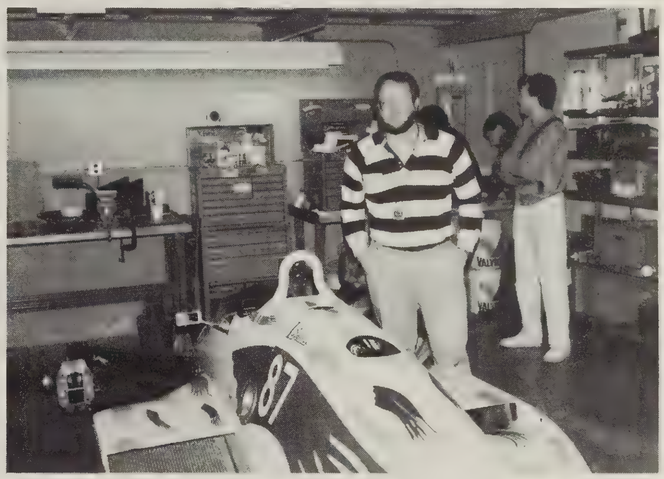
Dr. William M. Heller, Executive Director of the USP, received an Honorary Doctor of Science Degree at commencement ceremonies at the University of Maryland. Heller has served as MPhA Honorary President for 1986–87 and has led the USP since 1968. He received his M.S. and Ph.D. degrees from the University of Maryland.

Roslyn Scheer, Executive Director of the Maryland Board of Pharmacy, was elected to a three year term on the Executive Committee of the National Association of Boards of Pharmacy at its annual meeting in Seattle, Washington. She is the first non-pharmacist to serve on the NABP Board.

Howard Schiff (left), President of the Baltimore Metropolitan Pharmaceutical Association, receives a special leadership award from Frank Radigan (right) representing the Merck, Sharp and Dohme Company.



There was a car sponsored by a pharmacist in the recent Indianapolis 500 Race. The MediSpan Company founded by pharmacist Bruce Laughrey entered number 87 in the annual race. MPhA Executive Director David Banta had an opportunity to inspect the garage area.

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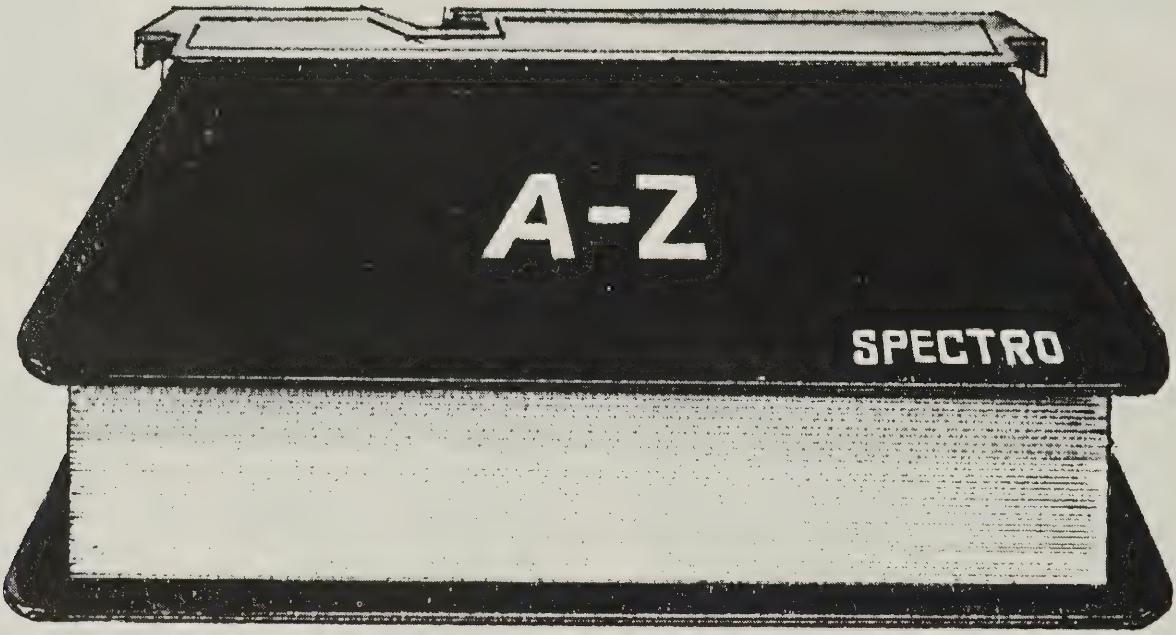

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Hotline for impaired Physicians (301) 727-0120

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

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3364

calendar

Oct 9–11—MSHP ANNUAL SEMINAR—WILLIAMSBURG, VA
Oct 18–23—NARD Convention
Oct 23–26—MPhA Trip to Nassau, Bahamas
Oct 23–25—Post NARD Convention side trip to San Francisco
Oct 25–Nov 1—APhA Midyear Meeting, Baltimore, MD
Nov 8—CECC Seminar on Hypertension
Jan 17–24 (88)—MPhA Trip to Curacao in the Caribbean

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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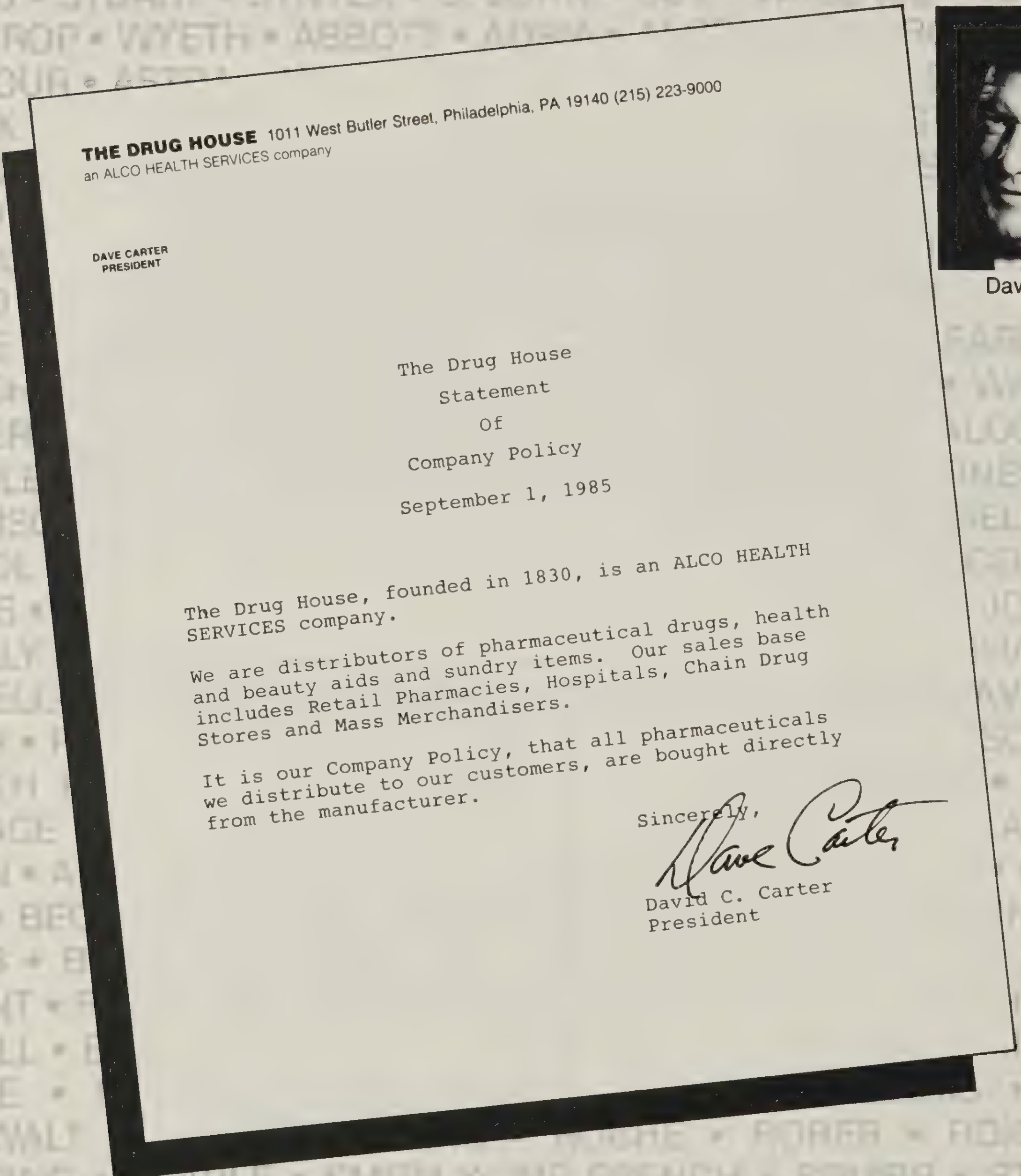

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PRESIDENT

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Dave Carter

David C. Carter
President

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THE
MARYLAND
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Official Journal of
The Maryland
Pharmacists
Association

August, 1987
VOL. 63
NO. 8

"Unconventional Memories" of the 105th Annual Meeting

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Reports
Resolutions

Ostomies and Ostomates—Part II

—J. Richard Wuest
—Thomas A. Gossel

The Pharmacist and Hospice

—Diane White
—Lynda Oderda
—Ilene Zuckerman

New Tax Laws; Bad Debts

—James R. Talley

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GUEST PRESIDENT'S MESSAGE

As I begin my term as President of the Maryland Society of Hospital Pharmacists, it gives me pleasure to address the Maryland Pharmacists Association. Over the years the two associations have maintained a strong professional relationship and I would hope to continue that practice during my term. Last year, MPhA and MSHP jointly sponsored an art auction to raise funds for the Maryland Pharmacists Rehabilitation Committee which generated $4500 in donations. Such an effort is evidence of the success the two organizations can have when working cooperatively.

I would like to share with you some of the issues that are facing hospital pharmacy practice today and that will be addressed by MSHP in the near future. A unifying theme for several concerns is the development of pharmacy as a clinical profession. The Hilton Head Conference of 1985 specifically addressed this issue and recommended that similar conferences be held on the regional level to define a plan whereby the profession can evolve into this role. Another issue being addressed by the American Society of Hospital Pharmacists which will be addressed by our Society, is the training, use and recognition of technicians in pharmacy. It will be necessary to elevate the level of practice of pharmacy technicians to allow pharmacists to achieve new professional goals. Also of concern, is the impact of the recognition of specialists in pharmacy practice. The Board of Pharmaceutical Specialities is currently considering a proposal to recognize clinical pharmacy as a specialty and is expected to receive petitions to recognize psychiatric pharmacy and oncology pharmacy practice in the near future. Finally, Maryland pharmacists and their associations must prepare for the new requirement for continuing education for pharmacists in this state.

The continuing evolution of pharmacy practice, the requirement for continuing education for practicing pharmacists in the state of Maryland, and a host of legislative concerns about pharmacy practice, all provide opportunities for cooperation between MPhA and MSHP. I trust we can continue to take advantage of these opportunities to jointly further the profession of pharmacy in the state of Maryland.

Professionally yours,

Paul L. Jeffrey, PharmD

President, MSHP

Bernard B. Lachman (right), Past President of the Maryland Board of Pharmacy, receives the Honorary Presidents Award from MPhA President George C. Voxakis (left)

Charles Spigelmire, shown with wife Josephine, was the recipient of the 1987 MPhA Distinguished Professional Achievement Award. He served as treasurer of the Baltimore Metropolitan Pharmaceutical Association for 32 years.

“Unconventional

Maryland Pharmacists

For the 105th Annual

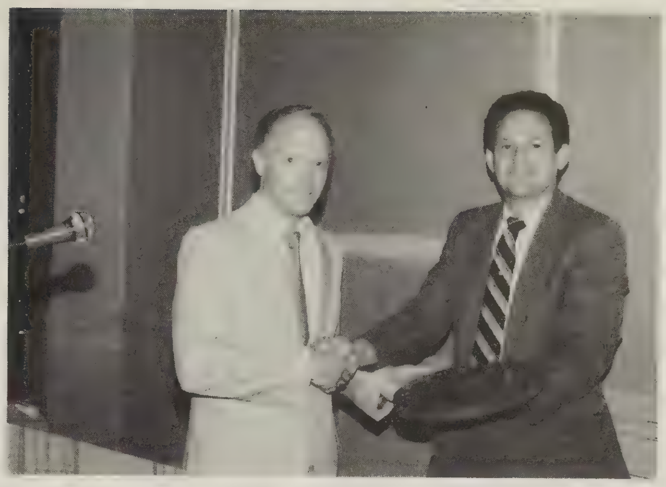
LAND
ACEUTICAL
ATION

The featured continuing education program was presented by David L. Schmidt on "Retaining Employees by Improving Morale." The 1987 Convention was a joint meeting with the Delaware Pharmaceutical Society.

"On your mark—" President George C. Voxakis prepares to cut the ribbon officially opening the Exhibit Hall. A total of 42 exhibitors participated in this years convention.

Exhibitors and convention attendees enjoyed a lavish breakfast in the convention exhibit hall each morning.

Paul Mueller (right) representing the A. H. Robins Co. presents the Bowl of Hygeia Award for community service to Oscar Schapiro (left) for his participation in emergency rescue work.



MPhA Past President Phil Cogan (right) presents the NARD Leadership Award to in-coming MPhA President Lee Ahlstrom (left). Phil served as the Toastmaster for the MPhA annual Banquet.

Memories”

gather in Ocean City, Maryland Meeting June 21–25, 1987

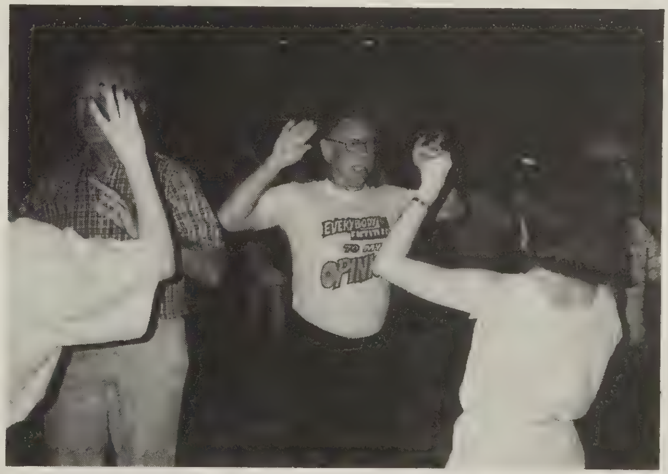
Pictures Courtesy of Abe Bloom

F. A. Davis

Richard Plotkin (right) of the Geigy Company presents the Pharmacists Mate Award to Sylvia Voxakis (left) at the Banquet.

POOL RULES
NO
TOWELS

The Spouses Auxiliary of the MPhA met several times during the convention. The anual breakfast and fashion show were well-attended.



The new Western Barbecue was a popular addition to this years convention. The square dance which followed resulted in some interesting pictures. (We are keeping all the negatives).

1987 Resolutions Submitted by The Resolutions Committee

Brian Sanderoff, Chairman

Resolution No. 1 (passed)

WHEREAS; changes in a patient's prescription drug insurance or Medicaid coverage can cause different mandates as to the brand of a drug product to be dispensed, and

WHEREAS; the indiscriminate switching of brands of prescription drugs, either brand name or generic, can be detrimental to a patient's health who is stabilized on a prescription drug product with a narrow therapeutic index,

THEREFORE BE IT RESOLVED that the Maryland Pharmacists Association supports the concept that the pharmacist should have the final authority to determine the ultimate version of the prescription drug to be dispensed to permit consistent drug therapy in the best interest of the patient regardless of changes in that patient's prescription drug coverage.

BE IT FURTHER RESOLVED that the Maryland Pharmacists Association take appropriate action to urge insurance companies to grant this authority to pharmacists.

Resolution No. 2 (defeated)

WHEREAS; it is generally agreed that certain prescription drug products and their generic versions can vary significantly in their bioavailability comparison data, and

WHEREAS; there is a plethora of generic prescription drug companies manufacturing the same version of generic prescription drug products, and

WHEREAS; it is vital that patients who are stabilized on prescription drugs with narrow therapeutic indexes be maintained on a consistent drug therapy regimen,

THEREFORE BE IT RESOLVED that all pharmacists be urged to consider the therapeutic advantages of maintaining a single source for a generic prescription drug product, regardless of marketplace and manufacturer price fluctuations.

Resolution No. 3 (passed)

WHEREAS; the Constitution and Bylaws of the Maryland Pharmacists Association has not been revised since 1977, and

WHEREAS; there are substantive modifications required to make this document reflective of organizational changes which have occurred in the interim and

WHEREAS; this document should be a living document, helping to guide the Maryland Pharmacists Association into the future,

THEREFORE BE IT RESOLVED that the Constitution and Bylaws Committee submit a revised version to this House of Delegates for its consideration at the 1988 Annual Convention.

Bria Sanderoff (left) accepts the out-going Speaker of the House Award for Gerry Epley, who was representing the Association at a national drug abuse training program. Brian presided over the business sessions on her behalf.

Resolution No. 4 (defeated)

WHEREAS; a portion of each regular Maryland Pharmacists Association member's dues is now designated to be applied for membership in an appropriate local association, and

WHEREAS; some of these local organizations are inactive or nonexistent,

THEREFORE BE IT RESOLVED that each member of the Maryland Pharmacists Association be given the opportunity to designate which local association, affiliated organization or pharmacy related activity that this portion of the dues amount be transferred to. These organizations could include the Maryland Society of Hospital Pharmacists, the Maryland Pharmaceutical Society, the Maryland Chapter of the American Society of Consulting Pharmacists, PharmPAC, the Maryland Pharmacists Association Scholarship Committee, the Pharmacists Rehabilitation Committee, the Kelly Memorial Building Fund, etc.

Resolution No. 5 (amended and passed)

WHEREAS; the incidence of A.I.D.S. is increasing rapidly in the general population, and

WHEREAS; the risk of infection is predicted to be reduced by the use of condoms, and

WHEREAS; Pharmacy has always supported preventive medicine,

THEREFORE BE IT RESOLVED that the Maryland Pharmacists Association support and encourage the distribution, promotion and advertisement of condoms.

Resolution No. 6 (defeated)

WHEREAS; the law requiring mandatory continuing education as a basis for relicensure has been passed by the State Legislature, and

WHEREAS; employees may wish to attend continuing education programs during scheduled work hours, and

WHEREAS; fringe benefits are a major portion of a pharmacist's employment package and could be a significant factor in the overall current pharmacist manpower situation,

THEREFORE BE IT RESOLVED that employers support the availability of continuing education opportunities for their employees by utilizing such methods as compensatory time, financial reimbursement or alternative scheduling.

Resolution No. 7 (passed)

WHEREAS; the state of Maryland has been selected for a pilot patient information project co-sponsored by the Maryland Pharmacists Association, the United States Pharmacopeial Convention and WBAL Television and Radio Stations, and

WHEREAS; this project represents one of the most important public relations projects for the profession of pharmacy in recent years,

THEREFORE BE IT RESOLVED that the Maryland Pharmacists Association urges each Maryland Pharmacist to actively participate in this public education campaign, and

BE IT FURTHER RESOLVED that the Maryland Pharmacists Association commend the United States Pharmacopeial Convention and WBAL-Television and Radion Stations for assisting in producing this outstanding community service project.

House Motion No. 1 (passed)
by William Skinner

I MOVE that Maryland Pharmacists be urged to contact their representatives in Congress and encourage them to support HR 2168, the bill to regulate dispensing physicians.

NEW BUSINESS RESOLUTIONS
Resolution No. 1 (amended and passed)
Submitted by Brian Sanderoff

WHEREAS; many pharmacists deal on a day to day basis with patients who have the potential of suffering from cardiac arrest, and

WHEREAS; the pharmacist is the most visible and accessible of all health care professionals to the public, and

WHEREAS; in the absence of another health professional in an emergency situation, the pharmacist would be expected to act appropriately.

THEREFORE BE IT RESOLVED that the Maryland Pharmacists Association urge all pharmacists to be CPR certified by the American Heart Association or the American Red Cross, and

BE IT FURTHER RESOLVED that the Maryland Pharmacists Association offer a CPR certification/recertification course at least once a year to all Maryland Pharmacists.

Nathaniel Futeral served as Chairman of the MPhA Legislative Committee.

Legislative Committee Report

Nathaniel Futeral, Chairman

After the dramatic successes of last year with SB 830, the bill to regulate dispensing physicians, the Committee approached the 1987 session of the Maryland General Assembly intent upon continuing the momentum which had been gained through increased grass roots pharmacist participation in the legislative process. While much was accomplished, there were also some disappointments.

The membership responded in a unprecedented fashion to a special call for funds to help support the retention of a full-time lobbyist for Pharmacy. This effort was especially encouraged by members of the Baltimore Metropolitan Pharmaceutical Association. However, shortly after the session had begun, we were dismayed to learn that our selected lobbyist had been appointed by the new Governor to the office of Deputy Attorney General for the State of Maryland. We thus inherited a valuable contact in the Attorney General's office but, at the same time, lost our head-start for the session. After reviewing the situation and the scope of the legislative package, the Board of Trustees concluded that the best course would be to continue our legislative effort as in previous years. The Pharmacy legislative effort is therefore poised for future accomplishments, having weathered the last-minute loss of our lobbyist and we gained valuable experience in working with the 1987 freshman session.

But there is good news. After many years of conversation about this issue, Pharmacy, as a profession, was again represented in the Maryland General Assembly with the election of Delegate Donald Elliott, a pharmacist from Carroll County. I was very pleased that he was recommended for the annual MPhA "Legislator of the Year" Award.

Also, following some very intensive efforts with the budget process for the Medicaid Program, which is reported elsewhere, a $.25 increase in the Medicaid Dispensing fee was preserved through all of the Legislative hearings.

The Association worked in close cooperation with a number of coalitions seeking worthwhile goals. These included the on-going coalition on tort reform which met with relative success. Pharmacy was again asked to support reform in smoking legislation as part of the Health Majority Coalition. And, of course, each year there are a number of bills which affect Pharmacy which cannot be predicted at the start of any one given legislative session. Constant vigilance is required.

But in the middle of the session, an issue arose which, once again galvanized pharmacy to united action. Of the 22 major licensed HMO's in Maryland, only one still retains exclusive agreements with chain outlets to the exclusion of all other pharmacy providers. Legislation was introduced in both the House and Senate (SB 1023 and HB 1472) to correct this situation. Very emotional testimony was delivered on all sides of this issue. There seemed to be very strong support for Pharmacy's position on this matter. Yet, there was also some concern with the precedent which would occur with the passage of "freedom of choice" legislation. The Legislature seemed to be giving the offending HMO some additional time to correct the situation, but the message has been delivered that there is considerable merit to our complaint. Progress is often measured in such small shifts. This will continue to be a high priority for the Legislative Committee.

I wish to thank all of the volunteers who took time to contribute to the efforts of the legislative Committee. I can think of no greater responsibility for this Association, acting in the best interests of our members, than to effectively represent Pharmacy in the governmental process. In today's society, effective representation is absolutely essential. I remain committed to establishing a lasting visibility for our profession among our elected officials. I will pursue the goal of establishing a "Mission to Annapolis" to allow motivated members to meet with, and influence the legislative process.

There is, of course, much more detail to our effort than can ever be conveyed in a single report. Those of us who participate in this process understand the personal rewards which can flow from this effort. Pharmacy, as a health care profession, has a tremendous credibility and respect in the State Legislature, but there is much which can be accomplished in the future. All of you are aware of the issues which confront us. You have only to read a trade publication to see how important to our very survival the legislative process has become.

I urge everyone here to volunteer to contribute to this effort. Of all of the Association's many efforts on behalf of the profession, this can be our most productive and challenging. Join us.

It has been my pleasure to serve as your Legislative Chairman. I would welcome the opportunity to serve again in some capacity. I would like to thank all of the members who volunteered to contribute to our efforts over the past year. It has been a vital learning experience for all of us. I would also like to express my personal appreciation to each of the MPhA Staff for their efforts. I could not have completed this final report without their invaluable assistance. Finally, I leave you with a challenge to each of you to recognize how important our combined efforts are to the final success of our legislative effort. Thank you.

DRUG UTILIZATION REVIEW (DUR) REPORT

Jean Hoffman, DUR Director

BACKGROUND

Although drug expenditures in Medicaid programs rarely exceed 7% of total program costs, the outcomes of inappropriate, excessive, or therapeutically incompatible drug use do have a significant impact on the costs associated with providing remedial hospital, physician, nursing home, and pharmacy services. In fact, a study by the Health Services Cost Review Commission revealed that, in 1983, the Maryland Medical Assistance Program paid a minimum of $1.6 million dollars for drug therapy-induced hospitalizations.

In an effort to prevent a significant number of drug-induced illnesses, the Maryland Pharmacists Association, along with the Medical and Chirurgical Faculty, entered into a partnership with the Department of Health and Mental Hygiene to perform therapeutically oriented Drug Utilization Review for the 380,000 Medicaid recipients in the State of Maryland.

Unlike traditional DUR programs which seek to reduce drug program expenditures, this DUR program addresses quality of care implications of drug therapy. The goal of this DUR program is to identify patients at "high risk" for drug therapy-induced illness, and to communicate those risk factors to providers responsible for a recipient's care.

In March of 1984, the Maryland Pharmacists Association in conjunction with Health Information Designs submitted a proposal to design, implement and operate a Drug Utilization Review Program. After much work by the members and staff of the Maryland Pharmacists Association and Medicaid, the DUR program was funded September 2, 1986 on a one-year renewable contract.

Jean Hoffman presents the first Drug Utilization Review program report to the Convention House of Delegates as the DUR Director.

IMPLEMENTATION

The DUR proposal called for a three month start-up period, followed by nine months of program operation. In the initial three months, four regional professional review committees comprised of practicing physicians and pharmacists were formed throughout the state. The committees are located in Baltimore, Easton, Central Maryland (meeting in Columbia) and Frederick. The professional committees were scheduled to be trained in November, however, due to computer problems, training sessions were held in December and January. Since January, the DUR committees have been meeting on a monthly basis to review computer generated profiles for therapeutic problems and clinical relevancy. The DUR Committee members are trained to review profiles for the following therapeutic problems:

1. Underutilization of noncompliance.
2. Overutilization.
3. Iatrogenic effects and adverse reactions.
4. Contraindicated combination use.
5. Drug therapy contraindicated by diagnosis.

Once a problem is identified, a copy of the patient's profile along with a letter outlining the Committee's findings is sent to providers involved in the case. The patient profile summarizes all medications received by the recipient along with all medical diagnoses for a 15 month period. The information is intended to assist the physician in evaluating a patient's drug therapy regimen while providing the pharmacist with necessary information so that he or she can more closely monitor a patient's drug regimen and consult with the prescribers.

To date, feedback from the provider community and Medicaid has been very positive. We know that we are making a positive impact on quality of care for the medicaid recipient, however it is still too early to calculate any costs saving to the Medicaid program.

ASSOCIATION IMPACT

The DUR program has had a significant impact on the Association office. Two additional staff members are now housed in the Kelly building, bringing the full-time staff up to 4 persons. To accommodate the additional staff, office space needed to be provided along with the acquisition of office furniture. The DUR office now resides in the space previously rented to the Episcopal ministry. Lease arrangements were arranged for a larger coping machine and an additional computer/word processing system, which are needed to process patient profiles and generate DUR letters and reports. Additional phone lines and equipment were installed. Along with expanding the MPhA office staff, the DUR program opens a direct line of communication between the office in Baltimore and the members serving on the regional DUR committees and the Medicaid Department.

ACKNOWLEDGMENTS

Without the dedicated support and efforts of many of the MPhA members and members of the pharmacy community, the DUR program could not have been implemented. The following people were instrumental in setting up the regional DUR committees:

Milton Moskowitz—Central Maryland DUR Committee
Richard Reitz—Central Maryland DUR Committee
Jim Rutten—Frederick DUR Committee
Tom Sisca—Easton DUR Committee
Ilene Zuckerman—Baltimore DUR Committee

Without the volunteer DUR Committee members, the DUR program would not exist. I would like to recognize the following committee members for their efforts and dedication to their professions:

Richard Baylis
Raymond Benack
Regina Carson
Jeffrey Cowen
Stephen Disharoon
Elizabeth Dixon
James Edwards
Dennis Ferguson
Jerome Fine
Murhl Flowers
Paul Freiman
Patricia Grunwald
Daniel Harris
Joseph High
Lisa Jaser
Joseph Jordon
Glenn Lichtman
Gary Magnus
Richard Reitz
Michael Rudman
James Rutten
Jeanette White
Lane Wroth
Ilene Zuckerman

ACADEMY of STUDENTS of PHARMACY REPORT (FORMERLY SAPhA)

Vice President—Bruce Greenberg

The Maryland Chapter of the Academy of students of Pharmacy has had a very busy and successful year. Student participation was at its highest level in several years and many projects were completed. Our fund raising efforts have started us off on good footing for next semester.

Our fund raising campaign has included several salad bars, t-shirt sales, and OTC Handbook sales. We also wish to thank the Alumni Association and the Maryland Pharmacists Association for their generous donations. Much of these funds were used to assist students attending the APhA Annual meeting in Chicago. Fourteen students attended the convention and enjoyed not only the sites in the city but the educational programs and interactions and many contacts made with students and pharmacists from across the country. The MPhA mid-year meeting in Annapolis was attended by some of our members. We will be hosting next falls APhA Regional Meeting on October 31 in Baltimore City. Students will be in charge of registration and entertainment. This will be a joint venture with students from Howard University.

Our Speakers bureau was also very active this year. Lectures were given on Pharmacy Residencies, Physician Dispensing, Drug Abuse & Impaired Pharmacists, The All Parm D issue, and Osteoarthritis & Calcium Absorption.

Our semi-annual Coffeehouse was held in May and was once again a hugh success. Our lampoon newspaper the UTC was published 5 times this past year, and proved that even with the students course load there was still some humor left in them.

ASP has enjoyed a helpful relationship with the faculty and staff at the school, and the staff at the MPhA, and look forward to this continuing next semester.

Beverly Yachmetz answered questions about the work of the Peer Review Committee following her report as Committee Chair.

PEER REVIEW COMMITTEE REPORT

Chairperson—Beverly Yachmetz

This year the Peer Review Committee received three complaints. Two complaints dealt with specific pharmacist's action and the third dealt with a pharmacy advertisement.

In both cases the letters dealing with pharmacists concerned medicaid prescriptions. The first letter concerned an early refill for a controlled substance, the other dealt with generic substitution. In both instances, when the pharmacist was contacted, the situation had been resolved to the satisfaction of the patient. Both pharmacists were extremely cooperative and were aware of the misunderstandings.

The final letter was a copy of a letter sent to the Board of Pharmacy concerning possible unethical advertising. After discussing this letter with Ms. Sheer, Executive Director of the Board of Pharmacy, it was decided this particular letter was an issue for the Board of Pharmacy. A letter confirming this decision was sent to the pharmacist registering the complaint.

This year there was an increase in the number of complaints received by the committee, however, the interaction between the pharmacist concerned and myself was very positive.

ANNUAL REPORT FOR YOUNG PHARMACIST CAUCAS COMMITTEE

Chairperson—Bradley Thomas

The Young Pharmacist Caucas (YPC) is a committee designed to help encourage pharmacists to become active in MPHA activities and provide timely information on various topics. The committee was started in September, 1985 by Madeline Feinberg, then President of MPHA, who also chaired it during its first ½ year. I was asked to lead the group beginning June 1986. My main task was the growth of YPC. The initial meeting included about 40 persons. The mailing list soared to 99, but when active membership was solicited the number dropped to 28. We now have a mailing list of 60 persons who are active. My hopes are to greatly increase the number when the recent graduates of UMAB-School of Pharmacy are solicited.

A few activities were sponsored during the past year. First, a CE program on nutrition was developed by members of YPC and held at the June 1986 convention of the association. That was a success according to the reports and evaluations received. Second, the committee scheduled a meeting at the wine and cheese get-together at this year's Mid-Annual meeting, but due to impending bad weather most people left. However, those that remained had a good time. Also we co-sponsored a Ski trip this winter which was an effort to attract younger pharmacists. Thirty people attended and had an excellent time skiing on Hunter Mountain in New York. We look forward to co-sponsoring other trips in the future including a white water rafting trip this fall.

The major form of communication is the YPC Newsletter of which I am the editor. There were four issues mailed. The topics ranged from politics to a law quiz. This coming year the newsletter will probably be expanded to include other sections on items of interest to the members.

By the time you hear this report, the updated version of the "Maryland Formulary" will be available. Contact the office for copies.

INDUSTRIAL RELATIONS COMMITTEE

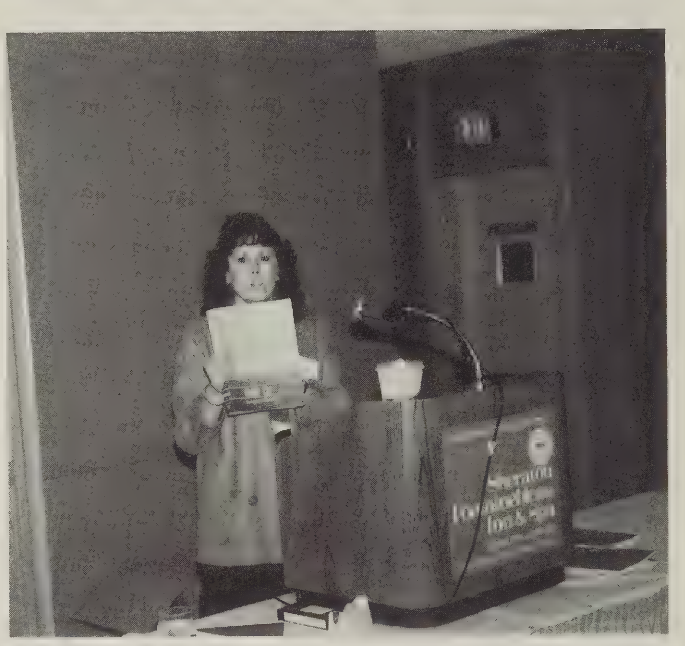
Chairman—Mark Golibart

The Industrial Relations Committee met once during the year to discuss the current issue of drug diversion. There has been considerable concern among members following the well-publicized FBI investigations in Georgia and Ohio. The Committee asked that the Maryland Congressional Delegation be urged to support HR1207, the bill to control drug diversion. This was done.

In addition, the Committee held discussions about the current state of the drug product selection act in Maryland. It was suggested that Pharmacists be reminded of the current law and considerations which should be followed in this proces. The law was reprinted in the *Maryland Pharmacist.* The Board of Pharmacy issued a new interpretation of the use of the "dispense as written" mechanism to say that physicians must indicate it in their own handwriting.

Finally, an article appeared in the Newsletter asking members who were aware of abuses in the area of diverted drug products to contact the Association. The Committee urges any member who has a concern related to the pharmaceutical industry to contact the Committee.

MPhA Kicks Off A Major Public Relations Campaign for Pharmacists at the Convention.



Alice Kimball, Director of Profesional Affairs for the United States Pharmacopeial Convention, makes the official announcement of the unique public relations project that is being co-sponsored by the MPhA, the USP and WBAL radio and television. Each Pharmacy in the State has received a copy of "Advice to the Patient" section of the USP-DI. WBAL is running public service spots on radio and television all summer urging patients to look for the publication in Maryland Pharmacies and to consult with their pharmacist. Posters and counter displays like the one on the facing page are available. The MPhA Public Affairs Committee, under the Chair of Phillip Weiner, is asking each Maryland Pharmacist to actively support this project. For more information contact the MPhA Office.

PUBLIC AFFAIRS COMMITTEE REPORT

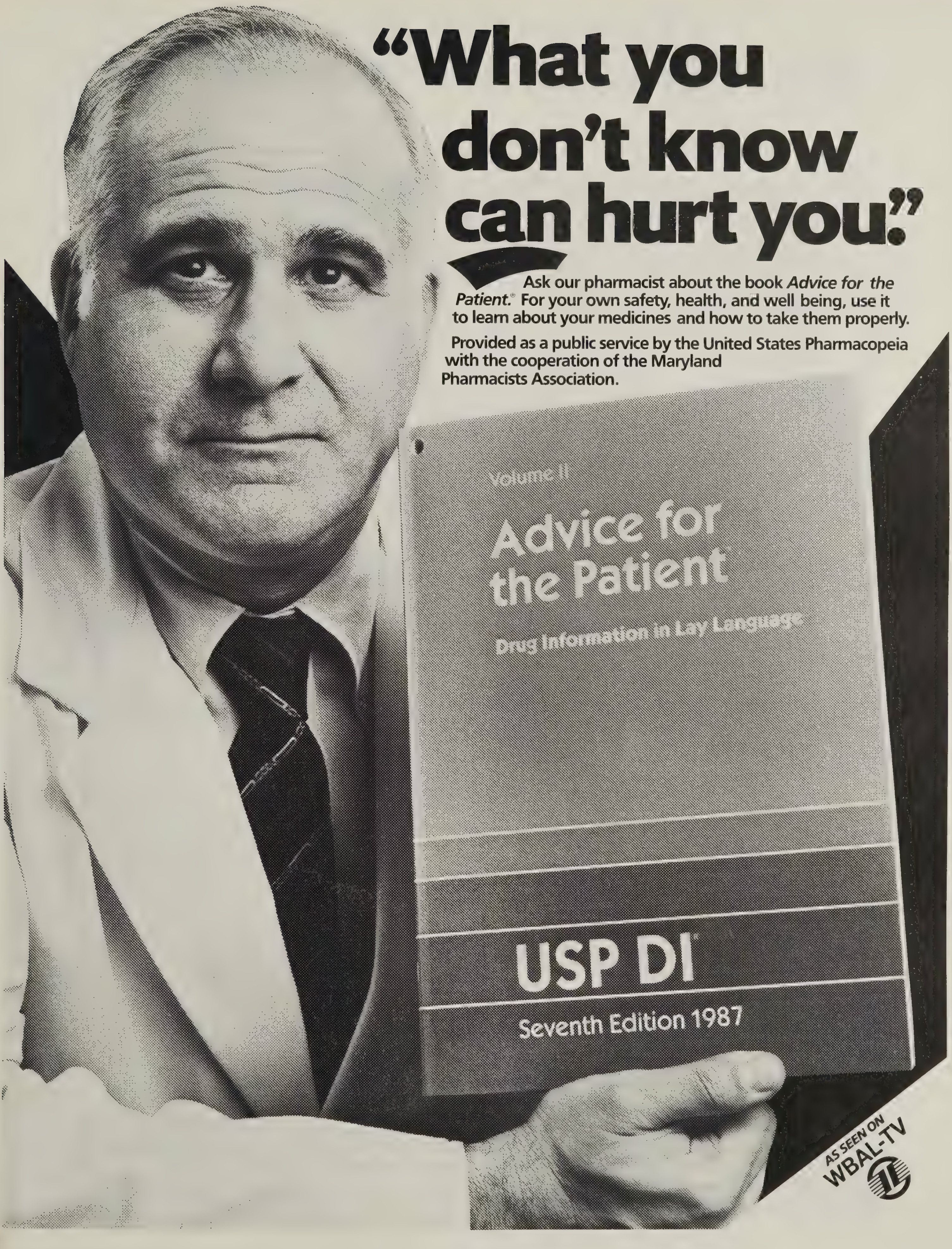
Chairman—Phillip P. Weiner

The Public Affairs Committee met several hundred times this past fiscal year. These meetings were usually held 6:15 AM or 7:30 AM in the home of the Chairman of the aforementioned committee. The meetings were generally cordial, considering the early hour.

"Your Best Neighbor" was broadcast twice each Sunday as usual. The times were changed twice during the year reflecting the views of a new program directress and the content of the programs. The time slots, I was told, were to be at more advantageous periods.

By the time this report is published, and if all went according to schedule, the project in concert with the USP should be in full swing.

The next year will hopefully bring new interviews to the public discussing as many facets of health care as possible.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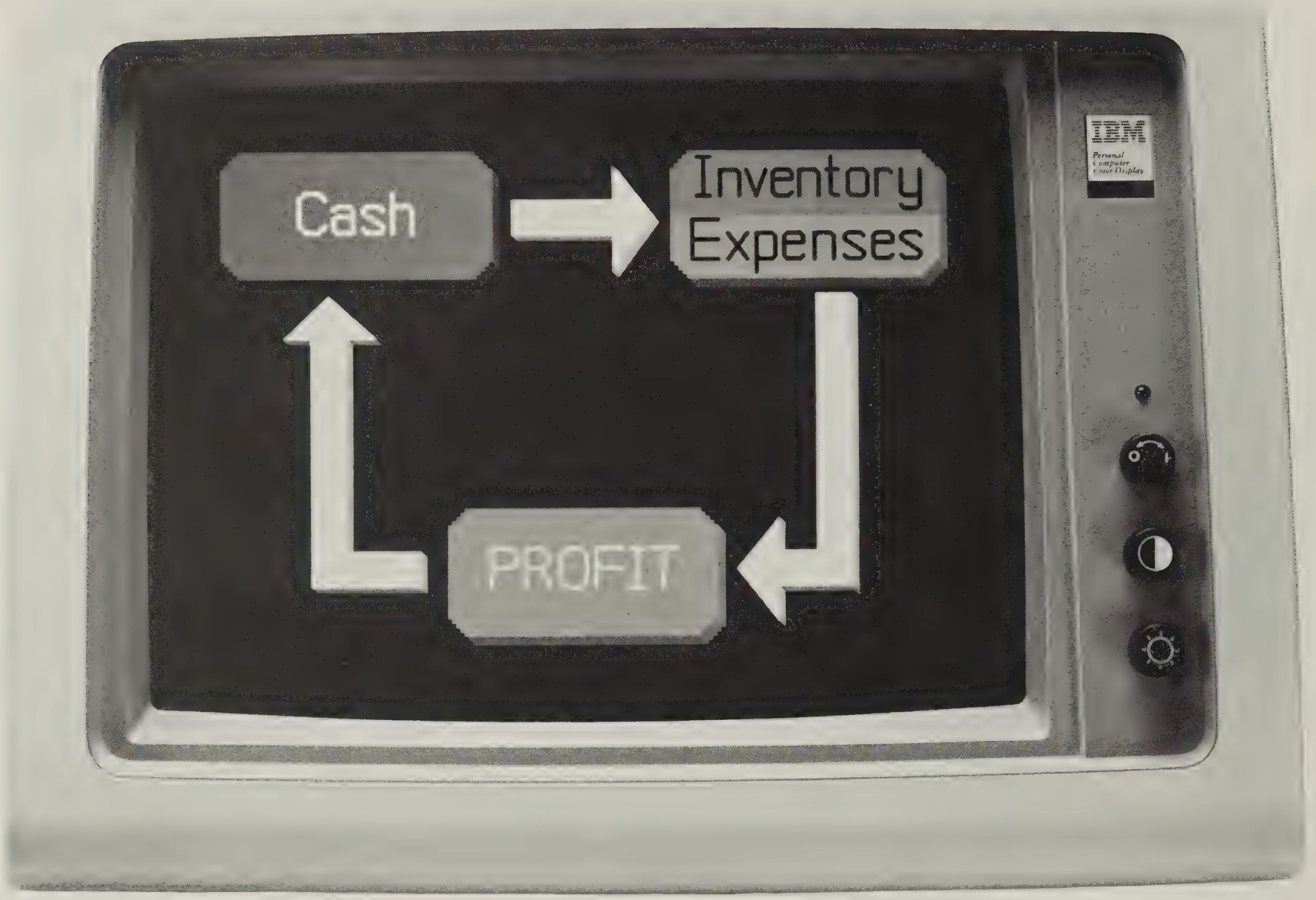

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National Association of Retail Druggists

CONTINUING EDUCATION FOR PHARMACISTS

Ostomies and Ostomates — Part II Patient Advice and Ostomy Products

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. discuss special post-surgical care the ostomate must perform to assure his leading a near-normal life; and
2. describe various ostomy appliances that are available for ostomy patients.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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Objectives

At the conclusion of this lesson, participants will be able to:

1. select specific foods that ostomy patients should avoid, or ingest with caution, in order to reduce complications;
2. differentiate between permanent and disposable ostomy appliances, and list uses and limitations of each;
3. identify the procedures involved in irrigating a descending colostomy; and
4. demonstrate knowledge that will assure that ostomy patients use their appliances and auxiliary products properly.

This article continues the discussion of ostomies and ostomates. It concentrates on the special care an ostomate must undertake to assure a near-normal life. It also discusses various types of ostomy appliances and auxiliary products, and presents advice for their proper use.

Post-Surgical Care

Diet is an important concern for all ostomy patients. It may require individualization, but restrictions should be no more severe than for a diabetic. There will be more limitations for persons with an ileostomy than those with a colostomy, since the latter still have most of their intestine intact and functioning.

Foods that cause diarrhea or gas should be avoided as much as possible. During the first several weeks after surgery, the patient will be placed on a low-residue diet to minimize the quantity of waste discharged. During the early months of rehabilitation, the ostomate should maintain a diet diary, experimenting with different types of foods.

Foods such as corn, celery, cabbage, coconut, nuts, and popcorn, which are difficult to digest, are best avoided because they may accumulate in the intestine and cause obstruction. If the patient desires to experiment, he should try small amounts, chew it thoroughly before swallowing, and drink lots of fluids.

Diarrhea can be troublesome to all ostomates. Ileostomates must be especially careful because of the increased danger of electrolyte loss and dehydration.

Foods which have a tendency to cause diarrhea include raw fruits and some vegetables such as broccoli, spinach, and tomatoes. Individuals may be able to control mild diarrhea with applesauce, boiled rice, strained bananas, or tapioca. Serious problems require medical attention.

The transverse colostomy reportedly results in the greatest amount of **gas** and **odor.** Although these should not be perceptible when the appliance is intact and tightly clamped, patients must change or air their appliances regularly. Gas-producing foods include peas, beans, corn, asparagus, broccoli, cabbage, onions, cucumbers, radishes, eggs, sausage, fish and carbonated beverages.

Since most gas results from swallowed air, patients should eat meals at a leisurely pace and chew with their mouth closed. Gum chewing and cigarette smoking also cause gas. Beer is a notorious gas-producer, and may act as a laxative.

In nearly all instances, ostomates can eat almost anything they wish. They must be aware of the problems encountered with certain foods, and be willing to accept the resulting diarrhea or gas. A drainable pouch should be worn when eating foods known to cause these problems.

There are several foods which may help reduce intestinal gas and odor. They include yogurt and buttermilk. Charcoal or bismuth subcarbonate tablets taken orally may also be helpful. Aspirin or chlorophyll tablets dropped into the ostomy pouch can reduce odor. However, some experts advise against this use of aspirin because of possible retrograde flow into the stomal opening, with irritation of it and the adjacent intestine.

Deodorant products (e.g., Banish™) that are inserted into the pouch, and odor-barrier disposable appliances are available. Another useful technique is to drain and wash the appliance, then rinse it with mouthwash. Urine odor in a urostomy bag can be reduced by adding 1 to 2 ounces of vinegar to the bag each day, or whenever it is drained.

Ostomy Appliances

Ostomy supplies are provided by dozens of manufacturers and are available in a myriad of sizes and shapes. Some are permanent, others disposable. Also, there are different supplies for the different types of ostomies.

Permanent Ostomy Appliances. These older and less frequently used appliances consist of rubber, latex or vinyl bags either attached to a faceplate (rubber disk) which is cemented to the skin or to a disposable skin barrier seal (Figure 1.). To change the former with the latter, the ostomate replaces the seal when it begins to deteriorate. Although the pouches with these sets are considered to be permanent, they have a normal life of 6 to 18 months, at which time they either wear out or can no longer be deodorized.

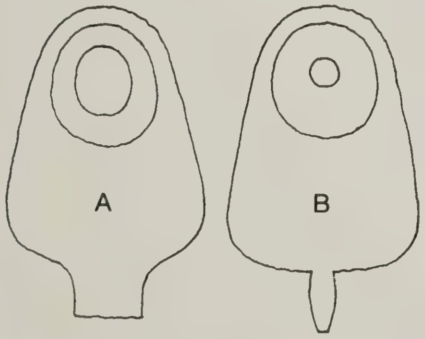


Figure 1. Permanent ostomy appliances. (A) wide opening for draining feces; (B) narrow opening for draining urine or liquid discharge

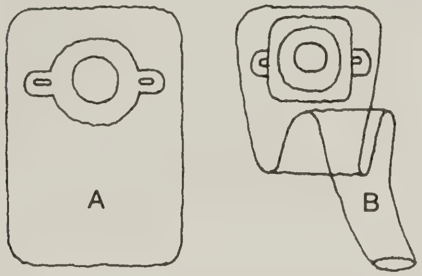


Figure 2. Disposable ostomy appliances. (A) closed end; (B) drainable

The ostomate should have 2 or 3 complete appliance sets and rotate them. They can usually be left in place for 2 to 7 days before changing. The extra sets allow time for washing, drying, and airing each appliance between use. As with rubber or plastic goods, completely drying and airing the unit prior to storage will greatly increase its lifespan.

Disposable Ostomy Appliances. These have gained greater acceptance, due mainly to their convenience and aesthetics. As with permanent appliances, disposables are available in both the closed and drainable types (Figure 2.).

Closed bags are intended for patients with descending colostomies. The drainable varieties are used for ileostomates, persons with an ascending or transverse colostomy, and individuals with an ileal conduit.

Disposable units are further subdivided according to the type of mounting rings used. Basically, there are seven types.

(1) The first is a two-piece combination unit consisting of a disposable bag suspended from a reusable mounting that can be attached to a cloth belt. The entire unit is replaced as needed.

(2) The next is a two-piece combination unit consisting of a flexible blanket-type skin barrier with adhesive that is worn on the skin for several days. The drainable bags are attached to a gasket fitting and replaced as needed. The blanket-type skin barrier is worn until it degrades and loses its barrier properties.

(3) The third type is a one-piece bag with adhesive surrounding the stomal opening, which can be pressed against the skin and worn without a belt. Several manufacturers use non-allergic adhesive to reduce the chance of dermal reaction.

(4) The fourth is a one-piece unit with an attached mounting gasket supported by a belt that does not require an adhesive.

(5) The next type is a one-piece unit similar to the above, but also containing a pre-attached inner ring of karaya gum or a blanket-type skin barrier.

(6) The sixth type is a one-piece unit containing the mounting ring or skin barrier and adhesive to offer extra protection from falling off. This type is especially useful to ileostomates. The products have either a spout or a sleeve-like opening at the bottom so they can be emptied without removing the bag. Between drainings, the sleeve is secured with a rubber band, tie string, or pastic clamp.

(7) The last type is a urinary drainage bag similar to the ileostomy drainage bag except that it tapers down to a valve which can be converted into a continuous drainage system by snapping on a detachable drain tube. The tube can be connected to a bedside urinary collector for overnight drainage. Figure 3. presents examples of typical urostomy appliances.

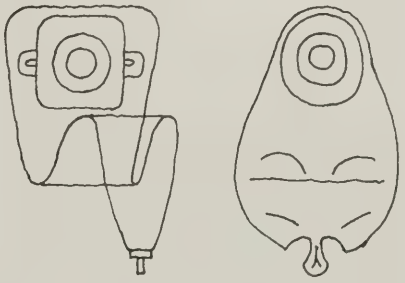


Figure 3. Urostomy bags

A loop ostomy requires a special type of appliance because of the large portion of intestine that is exposed and in contact with the skin. The skin barrier or mounting ring in this instance is more like a solid gasket, approximately 8-inches in diameter. The gasket is cut so that it fits as closely as possible around the exposed intestine. The mounting ring is supported by a belt and, once in place, drainage bags can be changed without moving the gasket or touching the stoma. The gasket can be left on until it shows signs of deterioration. It is then replaced.

Irrigation Appliances

Irrigating an ostomy (Figure 4.) is essentially similar to giving an enema, except that it is performed through the stoma. It is especially useful for patients with a descending colostomy, whose stools are well formed and have near-normal consistency.

The procedure involves suspending a container of lukewarm water (generally 500 to 1000 ml) at about shoulder height. The individual sits on the toilet and removes the soiled appliance or dressing. An irrigation bag is attached, with the long end placed into the toilet or a bedpan. Water is run through the tubing to remove all air. The catheter is then inserted into the stoma, and the water released. Flow rate should be adjusted for personal comfort; if released too quickly, it may cause rapid bowel distention with cramping. As with an enema, water adds bulk and mildly stimulates intestinal wall contractions, softens the stool, and facilitates its evacuation.

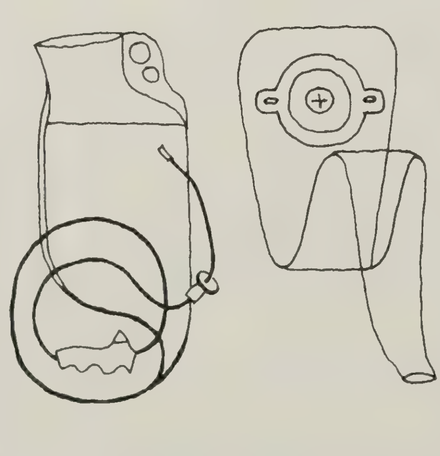


Figure 4. Ostomy irrigation set

Some patients seal off the drainage bag after the initial surge of returning fluid. They resume their normal activities while the stool softens and lubricates. They then return to the bathroom 30 to 60 minutes later to complete the procedure. Some colostomates wear a disposable pouch between irrigations. Others simply cover the stoma with gauze or a stoma cap.

If the individual is using the catheter system for irrigation, he should be extremely careful when inserting it through the stoma. There are no sensory nerves in the lining of the colon, and injury or rupture of the intestinal wall through diverticula or weakened areas may occur without him being aware of it. The catheter should be well lubricated and slowly inserted 2 to 3 inches.

A conical adapter that fits on the irrigation tubing is available, and preferred by many. With this adapter, the colostomate places the conical portion flush against the stoma rather than penetrating it with a tube. The water is allowed to run into the stoma. The safety features are obvious.

Patient Advice

Proper skin care is imperative for ostomy patients. It is easier to prevent dermal problems than treat them later. The skin around the stoma must be kept clean, dry, and free from contact with ostomy discharge.

The most common dermal problems are Candida infections, contact dermatitis, and skin excoriation (sloughing off) by digestive enzymes. Any of these conditions that persist or recur repeatedly should be evaluated by a physician. Candida infections respond to topical antifungal drug therapy. Contact dermatitis is treated by changing the appliance type or removing the adhesive tape or barrier substance and applying a topical steroid.

For ileostomies and ascending or transverse colostomies, the skin can be digested by enzymes contained in the fecal discharge. The resulting excoriation can accelerate to a vicious cycle. Blisters form and burst, roughening the skin and preventing an appliance from adhering properly. Therefore, the discharge causing the original problem makes it even worse. Applying a skin barrier and suitable appliance will help, because they conform to the shape of the roughened area, and permit the injured skin to heal. Powders and gummy pastes can be applied to seeping lesions to provide further protection against damage by digestive juices.

Basic cleanliness is extremely important to an ostomate, especially the ileostomate. The skin should be washed thoroughly with warm water and nonirritating soap, rinsed well, and dried. The stoma should be patted dry, but not rubbed. Gauze pads are good because they are soft; paper towels are too rough. For ileal conduit patients, moisture barriers, sprays or creams are helpful in protecting the skin from irritation by urine.

Skin Barriers. Several types of accessories are marketed for ostomy care.

Karaya is a natural gum resin which absorbs moisture, prevents leakage from the stoma onto the skin, and promotes healing. It can be applied over the inflamed skin and still allow healing. To use the powder, the skin around the stoma should be moistened with water. The powder is then applied over the wet area and the appliance pressed into place.

Other products such as Stomahesive™, Reliaseal™ and Hollihesive™ are also useful. They are blanket-type wafers composed of ingredients including gelatin, carboxymethylcellulose, and plastic materials with adhesive backing. They can be cut to the appropriate shape, and placed between the appliance and the skin.

Excessive heat can damage skin barriers, causing them to be misshaped and lose their resealing ability. They should be stored in a cool, dry place. Patients who are using skin barriers and continue to have recurring skin problems should be advised to see their physician. The problems may be due to incorrect use of the barrier, poorly fitting appliances, or an improperly located stoma.

Rehabilitation. Normally ostomates are able to return to former employment provided it does not require strenuous exercise or repeated heavy lifting. During the early days of rehabilitation, patients need as much psychological support as possible. Many ostomates, especially the ileostomates, have little trouble adjusting to their procedure.

Surgery is often welcomed because it removes the long-term incapacitating problems of ulcerative colitis or other serious pathology. If ostomates express concern about their inability to control bowel movements, they should be advised that their condition is not unique to them. Over a million American ostomates, including public personalities, performers and professional athletes, live near-normal, active and productive lives.

Ostomates may even take part, with moderation, in sports such as skating, tennis, golf, horseback riding, bowling, and swimming. In this latter instance, they must remember to protect their stoma from water and its contaminates. If a blanket-type skin barrier is used, it must also be waterproof because it may dissolve in the water. Watertight adhesive patches are available and should be used for such situations. Sports requiring excessive physical contact which may lead to injury of the stoma should be avoided.

No special type of clothing is necessary for ostomates. The modern appliances are easily covered and sealed. Girdles with rigid stays should be avoided because they might exert excessive pressure on the stoma.

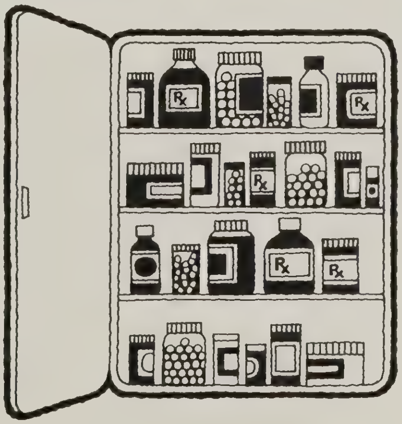
Ostomates may be concerned about sexual activities. Mental attitude has a tremendous effect on sexual desires, performance, and success. Male patients, especially those with ileal conduits, may occasionally be rendered sterile. But as a rule, once he and his partner have overcome the psychological barriers, sexual relations are not impaired.

Female ostomates may bear children. However, because of the physical problems of carrying a child, and the need to be in good physical condition, she should wait at least one year post-operatively, and discuss the matter with her physician beforehand.

Travel. Having an ostomy should not alter the patient's traveling or vacation habits as long as he plans properly and takes along adequate supplies. When traveling outside the U.S., water supplies should be watched closely since dysentery will cause the patient excessive trouble. Water which is unsafe to drink will be unsafe to use to irrigate an ostomy. If there is any question about the water, it should be boiled before use. The U.S. Public Health Service can provide necessary information concerning contamination and safety factors of water supplies in foreign lands. The patient should check this out before he leaves home.

The ostomate will be aided psychologically by resuming whatever socializing, recreation, or traveling that is possible after convalescence. There is little reason why an ostomate cannot live a near-normal life if activities are carried out in moderation.

The best qualified person to psychologically aid the patient before and after surgery is another ostomate. The United Ostomy Association (2001 West Beverly Boulevard, Los Angeles, CA 90057) is dedicated to helping ostomates help one another, and publishes a journal containing many helpful hints. Most metropolitan areas have local chapters whose members meet on a regular basis. Patients having psychological problems should be informed about the organization and encouraged to contact it for assistance. The American Cancer Society can also be contacted for information about local groups.



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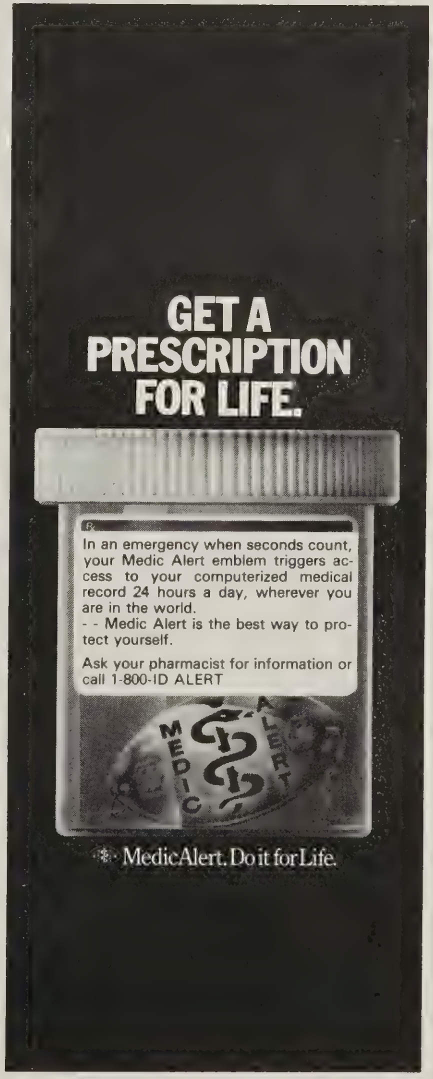

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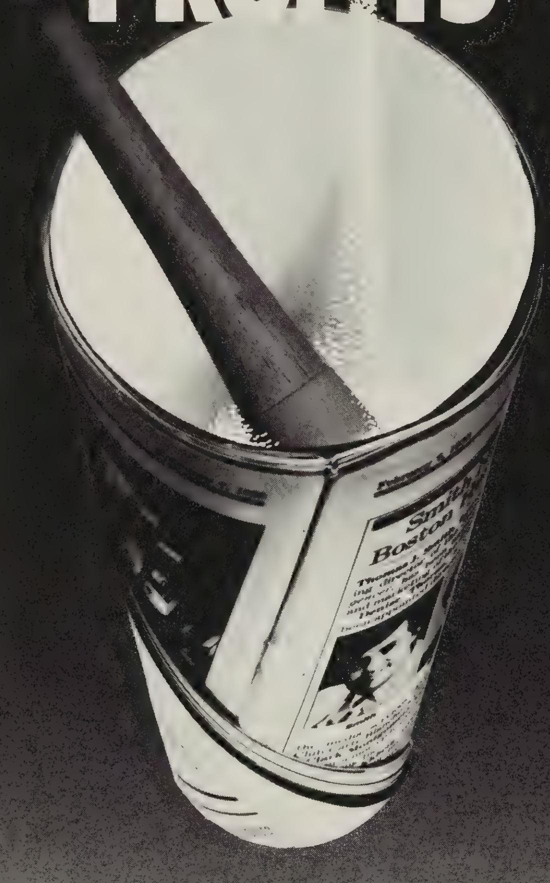

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Continuing Column

The Pharmacist and Hospice

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VI

IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

Dealing with hospice patients can present some challenges to pharmacists, both professionally, as well as personally. Many people, including health professionals do not like to think about death. However, as we deal with this topic fairly frequently when actively involved in hospice, it is a topic that does need to be thought about. Taking the time to think about one's own feelings on the subject of cancer, death and dying may give some insight into how others react when they are faced with these same problems. However, one should realize that no matter how much thought has been given to the subject, one can never fully appreciate exactly what the dying person is feeling. The following case illustrates this point.

Patient E.O. is an elderly woman in her mid 50's who was diagnosed as having metastatic breast cancer over one year ago. She worked full-time up until 6 months ago as a clerk typist, when she was forced to retire because of weakness and side effects of her drug therapy.

During a recent home visit, E.O. began to describe her feelings of frustration and loneliness. She stated that she was not afraid to die because of her strong belief in God. However, she expressed feelings of frustration with her situation because of her relatively new dependence on people to do even the simplest tasks. She had always prided herself on her independence. She was also fully aware of how much of a burden she placed on people, since she had had to take care of her own mother for ten years. Her mother had also died from cancer. Because of her own previous experience of caring for a sick, elderly relative, she expressed understanding for the feelings of her own family who are now responsible for taking care of her.

While talking about the loneliness, E.O. began to cry very quietly . . . it wasn't obvious, just one tear going down her cheek, since she kept her head averted during our conversation. But she talked quietly about the fact that for someone who had led a very active life previous to her being homebound, it was very hard to accept this new solitude. She said that people did come to visit, both friends and relatives; however, the visits never seemed to last long enough for her. Because of her failing eyesight she can no longer read, which was something she enjoyed doing in the past.

Finally, E.O. talked about the fact that only her one friend who also has a terminal illness truly understood how she felt. She said that people she talks to say "I know how you feel" or "I understand how you feel," but she said no one really knows how I feel because they haven't experienced all the pain that I do every day. E.O. didn't sound angry when she was talking about her feelings, just tired and resigned.

In summary, when talking with an ill patient, keep in

New Tax Laws: Bad Debts

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School of Pharmacy
Northeast Louisiana University
Monroe, LA 71209-0470
(318) 342-3065

Bad debts can be devastating to your pharmacy. Under the "old tax laws" it was possible to utilize the "reserve method" to write-off bad debts. However, the "reserve method" has been eliminated from the "new tax laws." The "reserve method" had enough flexibility to allow a business (your pharmacy) to claim bad debt deductions on the basis of projected rather than actual losses. In some instances, this resulted in deductions which were greater than losses. Thus, it allowed a business (your pharmacy) with a historically percentage loss of receivables due to bad debts to establish a reserve equal to that dollar amount at the end of the tax year.

For example, if your pharmacy had receivables of $500,000 with a historical loss of 5% of receivables due to bad debts, then the reserve write-off would be $25,000. This advance write-off resulted in an interest-free loan from the IRS because the shortfall was subtracted from the following year reserve.

However, this option no longer exists because with the "new tax laws," bad debt deductions will be limited to proven uncollectibles in the tax year claimed. For example, if your pharmacy had $10,000 in bad debts, you would be limited to a $10,000 deduction in the "year" the debts converted to bad debts. Thus, a debt must be deducted in the tax year it was declared "worthless" and failure to exercise the write-off can result in loss of the bad debt deduction.

By now you probably are asking questions with regard to: what is a bad debt; how do you prove a debt is uncollectible; and what are the qualifications for the write-off. An excellent rule to follow would be to exercise prudent business judgment in regard to credit and collections. In other words, just feeling that the account would not be paid or sending a single dunning letter, may not qualify for a bad debt deduction. This means that your pharmacy should have a formal "in-house" collection process or refer the account to outside collection professionals. Thus, the effort expended in collecting a bad debt is more important than the length of time the debt is outstanding.

It is a sound business practice to take a systematic approach for credit and collections. Experts in this area have suggested the following:

- Bill accounts in advance of the due date
- Clearly state your payment terms and conditions
- Send a follow-up invoice immediately after the payment date to remind the debtor of their obligation
- If payment is not received in 45 days, send a reminder notice
- On about the 75th day, follow-up with a warning that the account will be turned over for collection
- After 90 days, refer the account to a collection agency or an attorney specializing in debt collection (Note: many of these professionals work on a contingent fee basis which means you are not charged unless they collect)

It is extremely important that you document all steps in the collection process. This should include maintaining copies of correspondence and a log of telephone calls. Remember, you may need to prove to the IRS that you exercised prudent actions to recover the debt. Please note that this is an overview and you are advised to consult your tax attorney or CPA for specific details.

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mind that it is best to avoid telling them I understand, unless you have had a similar experience.

See recommended readings:

UNDERSTANDING GRIEF
by Edgar Jackson.
Nashville: Abingdon Press, 1957.
Discusses the "roots, dynamics and treatment" of grief.

ON DEATH AND DYING
by Elisabeth Kubler-Ross.
New York: MacMillan Co., 1970.
Describes five stages of dying.

GRIEF COUNSELING AND GRIEF THERAPY
by William Worden
New York: Springer, 1982.

There is a toll-free number to call (1-800-4CANCER) Mondays through Fridays during working hours for information related to cancer. When closed, the caller is directed to call 1-800-492-6600, the Cancer Information Service, a program of the National Cancer Institute. This service provides answers relating to cancer, including current protocols using investigational therapy, where such research is being conducted, etc. Counseling, literature searches and free brochures are also available.

EXECUTIVE DIRECTOR'S REPORT

David A. Banta, C.A.E.

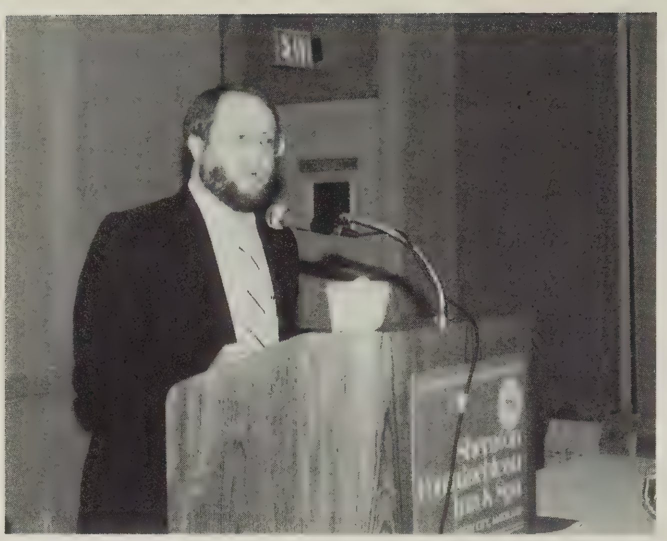
This is the tenth year that I have had the privilege to serve you as Executive Director of the Maryland Pharmacists Association. The time has been personally and professionally rewarding for me and productive for the Association. I wish to thank all of the volunteer leaders, the officers and trustees, committee chairmen, and involved members for working together to make the MPhA one of the finest state pharmacy associations in existence. We have accomplished much for the profession. I am pleased with and proud of our record.

Each year, a new administration, under new leadership takes up the responsibility of presiding over the work of the Association. George Voxakis has had a very successful year as President. Perhaps the most important event for the Association occurred after three years of waiting and hard work when the MPhA initiated the contract to perform Drug Utilization Review for the Medicaid program. While we had planned for this for some time, the changes that it brought about were truly dramatic. It has increased the Staff resources of the Association through the additions of Jean Hoffman as the DUR Director and Director of Professional Affairs and Dawn Ranger, the DUR Secretary. The contract has permitted the Association to expand its physical resources as well. The office currently has three computers, a new copier, and expanded desk and secretarial space.

The next most important change was the formation of the for-profit subsidiary of the Association, the Prescription Network of Maryland. This separate organization will allow Pharmacists to compete in the marketplace for prescription drug business which had been lost to mail order plans, exclusive agreements or other harmful cost containment schemes. For the first time, we will be actively marketing the services of a network of pharmacies to purchasers of health care without the previous concerns of violating the antitrust laws. As part of this development, a third party claims company, D and P Processing, has also moved into the Kelly Memorial Building under the auspices of the Prescription Network of Maryland. As PNM acquires contracts, we anticipate that even more staff will be required in the Association headquarters.

The working relationship with the Maryland Society of Hospital Pharmacists continues to improve. MSHP has moved its mailing address to the Kelly Memorial Building. It has donated one of the office computers, installed its own telephone line and contributes to Kelly Building upkeep. The MPhA and the MSHP co-sponsored a successful art auction fund-raiser for the Pharmacists Rehabilitation Committee.

On the legislative front, the Association kept in the State's budget the $.25 increase in the Medicaid dispensing fee which will go to $3.70 on July 1, 1987. We were the only Medicaid provider group to receive an increase this year. The biggest battle this year was over the issue of freedom of choice in HMO's. Of the approximately 22 licensed HMO's in Maryland, only one major HMO has exclusive agreements with chain outlets to the exclusion of all other pharmacies. There was a great deal of support for the MPhA position on this issue and, while our bills were ultimately not passed, a clear message was sent to the offending HMO and the Legislative Committee fully expects that the situation will change or the legislation will be adopted in the next session. MPhA continued the battle over the dispensing physician issue and there are now proposed regulations from the Board of Medical Examiners which will implement the previously won SB 830. Due, in part, to the publicity generated on this issue in Maryland, and the intervention of the Federal Trade Commission, Congress has begun to focus on this matter.


Executive Director, David A. Banta, delivers his tenth annual report to the House of Delegates.

These are just a few of the accomplishments of the past year. As you read over the other Officer and Committee reports, I hope it is evident that the MPhA continues to be a vibrant organization which is constantly changing to be more responsive to the needs of the members.

As required by Association policy, I would now like to comment on the disposition of the Resolutions which were adopted by the 1986 MPhA House of Delegates at last year's convention. Resolution number one required the Association to continue its efforts to regulate mail order prescription drug programs and to educate the public on this issue. While the Legislative Committee determined that a specific bill should not be introduced in the last session of the Maryland General Assembly for a number of complicated reasons, this issue continues to be a high priority with the Association's leadership. Public education material was developed and distributed directly to the public. This information was also made available to pharmacists through the *Maryland Pharmacist.*

Resolution number two called upon the Association to compile a list of continuing education opportunities and publish the results. Such a survey is currently being conducted.

Resolution number three requested that manufacturers be requested to furnish pharmacists as well as physicians with specific information when an emergency exists with a drug product. This request was given to the Pharmaceutical Manufacturers Association and was shared with their member companies.

Resolution number four was tabled. Resolution number five required the Association to actively support Medication Awareness Month in October, 1986 and this was accomplished.

Resolution number six requested the Association to seek modification of the Federal Non-Profit Institutions Act to prohibit unfair competition in the retail marketplace. MPhA continues to work with the national associations and Congress on this issue.

Resolution number seven requested the Association to support the concept of a single uniform price from drug manufacturers. This position was widely publicized in Association literature and shared with the Pharmaceutical Manufacturers Association.

Resolution number eight requested that the practice of physician drug sampling be replaced with a coupon or voucher system so that the patient might receive the drug from the pharmacist at no charge. Working with the national associations, the MPhA encouraged them to include this concept in the testimony which was given on the Prescription Drug Diversion Act (HR 1207).

Resolution number nine requested that the Association seek methods for eliminating prescription price advertising of all controlled substances. The Association leadership is still exploring the legal review and implementation of this resolution.

Finally, I would like to thank all of the professional people I work with who make up the staff of your Association. It has been my great pleasure to work with Beverly Litsinger, our Office Manager and this year's Honorary President of the Alumni Association, Mary Ann Frank, our Comptroller celebrating twenty-five years with the Association; and our two newest staff members, Jean Hoffman, DUR Director and Director of Professional Affairs and Dawn Ranger, DUR Secretary. They make it all possible and have my deep appreciation.

REPORT OF THE UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY

by William J. Kinnard, Jr., Dean

A decision not to make a change, innovative new programs, nationally and internationally known guest speakers, and faculty and student honors highlight the activities in the School of Pharmacy during the past year.

The Faculty, following a lengthy debate, decided not to adopt the Pharm.D. degree as the only professional degree offered by the School. The continuation of the present two degree system was approved along with an agreement to give more emphasis to the more advanced aspects of those programs.

Two cooperative ventures with UMBC have resulted in the establishment of important and innovative programs. The Center for Drugs and Public Policy, headed by Dr. David Knapp, will conduct research on the use and misuse of prescription drugs and assess how public policy regarding those findings can be formulated and implemented. Dr. George LaNoue of UMBC's Public Policy Graduate Program is chairman of the board of advisors. Another joint venture is the Fermentation Microbiology/Engineering Group which faculty from the Department of Medicinal Chemistry/Pharmacognosy (Drs. Marilyn Speedie and Burton Pogell) has formed with UMBC's Chemical Engineering Department. This effort is part of the University's Biotechnology program.

Research and training programs related to pharmacy practice were an important activity of the School during the past year. Dr. Peter Lamy, and others from the Department of Pharmacy Practice and Administrative Science, initiated the Rural Pharmacy Program in Geriatric Pharmacy. Over two hundred and fifty pharmacists from five states participated in the training program. Dr. Donald Fedder began a 10 month pilot program involving ten pharmacies to test a new computer activated reminder system to help hypertensive patients to become more compliant in the refilling of their prescriptions. Dr. Frank Palumbo continued his study of antibiotic use in nursing homes, and Dr. Alan McKay started a study of the factors influencing the opening and survival of new independent community pharmacies. Dr. Ilene Zuckerman from the Department of Clinical Pharmacy, becoming nationally recognized for her work in home care, conducted a training program for pharmacists involved in hospice care. Dr. Ralph Shangraw, Chairman of the Department of Pharmaceutics, working with Dr. C. Jelleff Carr, published a report comparing the dissolution and disintegration rates of many brand name and generic calcium supplements. They received national press coverage on their work. The Maryland Poison Center, under the leadership of Dr. Gary Oderda, participated with Johns Hopkins Applied Physics Laboratory in the early stages of development of a computer to assist with the diagnosis and treatment of poisoning victims. The Poison Center, by the way, received 50,354 calls in 1986.

The research programs of the School have continued to grow. Last year the School received over one million dollars in grants and contracts, the second highest level of all the schools on the UMAB campus.

The School combined its three endowed lectureships (Balassone, DuMez, and Grollman) to host a special day and a half symposium on "The Cocaine Epidemic: Implications for Professionals." Drs. Herbert Kleber of Yale, David Smith of the Haight-Asbury Clinic in San Francisco, and Jerome Jaffe of the National Institute of Drug Abuse were the main lecturers.

Faculty and alumni received a number of honors. Dr. Dean Leavitt was named the Honored Alumnus by the Alumni Association, and also was awarded the UMAB Student Affairs Award for Exemplary Service; Dr. Esam El-Fakahany received a five year Career Development Award from NIH; Dr. David Knapp won the prestigious Volwiler Award from the American Association of Pharmaceutical Education; and Dr. William Heller, an alumnus and Executive Director of the United States Pharmacopeial Convention, was awarded an honorary Doctor of Science degree at this year's UMAB Commencement.

Our students continue to achieve national recognition. Donna Eby, Mary Beth Fiedel, Thomas LaMartina, Judy McKay and Rhona Robinson won a $2400 grant from the NARD for their special projects. The United States Information Agency (USIA) followed one of our students, Phillip G. Price, through his various educational experiences, taking photos for a major article on pharmacy education in the United States that will be published in *America Illustrated*, a publication distributed throughout the Soviet Union.

This past May, during the commencement ceremonies, we awarded the following degrees: 64 B.S. in Pharmacy, 10 Pharm.D., 3 Masters in Science, and 10 Ph.D. We enlarged our entering baccalaureate class size for the Fall of 1986 to 100 students in recognition of the shortage of pharmacists, and will continue to enroll an entering class of that size as long as the need exists and an appropriate applicant pool is available (1987 applicant pool was 275). In spite of the large number of well qualified applicants for our programs, we still need the help of all practitioners to identify well qualified, highly motivated men and women for admission to our School.

Coupon Redemption Program

Mary Ann Frank, Comptroller

The Mid Atlantic Food Dealer Association (MAFDA) was started on May 1985. The first year 55 stores signed up.

In 1986 the program generated a gross income of $5661.45. After expenses a profit of $2450.52 was realized.

The program now has 77 acitve stores participating. A 30 day turn around plus a rebate up to 3 cents per coupon makes the program very attractive.

PHARMACISTS REHABILITATION COMMITTEE ANNUAL REPORT

June 12, 1987

Harry Finke, Co-Chairman

I. Introduction:

The Pharmacists Rehabilitation Committee was formed in response to a perceived need to establish a middle ground between a pharmacist's dysfunction in practice and license suspension or revocation by the Maryland State Board of Pharmacy. The Committee contracted its first treatment agreement in October 1983. The purpose of the Committee is to intervene and take appropriate action so that the impaired pharmacist can have a chance to address the dysfunction appropriately and save his/her career and preserve their mental and physical well being. The goal is to act as swiftly as possible to insure that the pharmacist obtains proper counseling and medical treatment. Pharmacists who desire the advocacy strength of the Committee must enter into a signed contract with the Committee. Information is maintained in complete confidence, protected by law, separate and apart from any Association or State Board records. Following a successful rehabilitation all records are purged from Committee files.

II. Progress Report:

1986–87 was earmarked as a fund-raising year. In our previous annual report (May 28, 1986) financial concerns were discussed. Specific needs included financing a part-time program coordinator. With the generous help of a variety of groups and organizations including the Maryland Pharmaceutical Association, the Maryland Society of Hospital Pharmacists and the Pharmacy School Alumnae Association the fund-raising efforts were a resounding success. Our appreciation is expressed to all those who contributed through the voluntary checkoff of support when renewing their association membership. In May '86 we reported raising $2,000 in contributions. Our current financial report shows a balance of over $11,000! In addition to the organizations listed above, individual contributions were received from A.I.D. Drugs, Good Samaritan Hospital, Merck and Co., Revco, and Merrell Dow Inc. Plans for the disbursement of these funds is discussed below.

The success of the fund-raising efforts can be broken down into three areas: First both the MPhA and the MSHP have included a voluntary checkoff to allow members to contribute directly to the Rehabilitation Committee. Second, we continue to receive donations from individuals, and businesses. Third, the MSHP masterminded and produced the single largest fund-raising event, an art auction that netted roughly $3,500 for the Committee. We are very grateful for these efforts and the support they provide.

Perhaps the single most important accomplishment is the hiring of a part-time program coordinator. Ms. Henrietta Bond, M.H.S. was brought on board in October. She comes to serve the Committee with years of chemical dependence treatment and intervention experience. Her vast knowledge of addictions intervention is attested to by the fact of her position as a faculty member of Lincoln University, a well known advanced training program for the social sciences and her position as a research associate in the University of Maryland School of medicine. She has developed and implemented a process for maintaining data that will improve the advocacy power of the Committee.

Harry Finke explains the progress that the Pharmacist Rehabilitation Committee has made over the past year. The Committee has been able to retain part time professional staff.

Two Committee members attended the Regional Meeting of Pharmacists Interventiion Committees in Lancaster PA in November. It was held in conjunction with the National Association of Boards of Pharmacy convention. A presentation to the NABP on the positive aspects of Pharmacy Rehabilitation Committees was received with such enthusiasm that NABP donated $5,000 to the Regional Committees. Our Committee Chairman, Harry Finke, has been elected by the Regional Committees as the Co-Chairman of the finance committee and treasurer for the region. Another outcome of the regional meeting is the acquisition by our Committee of a video tape that will be used both in individual interventions with pharmacists and as a general educational piece.

Our Committee participated in the planning of the Interdisciplinary Conference on Impaired Professionals which attracted some 300 participants from all health disciplines. In addition our members have made presentations to various pharmacy professional organizations publicizing the work and purpose of the Committee.

We are once again investing in the future of the Committee by sending two members to the University of Utah School on Alcoholism and Other Drug Dependencies in June. Since two members attended last year we expect that this will enhance the Committee's skill level overall.

III. Treatment Report:

During the year since our last report the Committee was involved with 17 new contracts. Of these, 11 resulted in contracts being signed agreeing to intervention and treatment. There are 20 active cases in treatment. This year we are happy to report the successful recovery and contract completion of 8 pharmacists.

The availability of funds has made it possible for the Committee to pay for screening evaluations by chemical dependency specialists, so vital to accurate case assessment and effective treatment planning.

IV. Annual Plan:

In the coming year we plan to address two primary concerns. First, to expand the Committee as a functional program beyond the Baltimore metropolitan area. A recently donated 1-800 telephone mailbox will be advertised and promoted. In addition, a more aggressive campaign will be launched with the knowledge that the funding is available to support such an expansion. We may consider increasing the program coordinator's time if necessary, based on an increased caseload.

Second, we are targeting employers especially, for a continuing education program. If pharmacists in recovery are to return fully to the practice of the profession, employers must understand the Committee's work and the capabilities of the recovering pharmacist. We have broached this topic with continuing education planners and have received a favorable response. We hope eventually to establish a pool of employers who would be open-minded and lead the profession in rehiring the recovering pharmacist.

An ongoing need is the recruitment of interested pharmacists, sensitive to the Committee's work, into voluntary participation as Committee members.

V. Summary:

After a successful fund-raising year we are now in the planning stage to determine how best to utilize the monies donated so generously by the pharmacy community. There will be obvious expansion efforts including educational programs and aggressive publicity. We hope to be equally accessible to pharmacists on the Eastern Shore and in Western Maryland as we are to those in the Baltimore Metro location. We hope to encourage pharmacy employers to understand that the profession is best served by pharmacist rehabilitation and rehiring, while the practice of firing a dysfunctional pharmacist without intervention only increases the risks of hiring another dysfunctional professional as their replacement.

VI. Appreciation:

We wish to thank all those who have contributed time, effort, and money to the Committee's work and regret not being able to acknowledge each gift individually in this report. Special thanks are in order to the MPhA, MSHP, and the University of Maryland School of Pharmacy for support.

The Committee recognizes the volunteer time and effort of the following volunteers:

Gil Cohen, Steven Cohen, John Davis, Gerry Epley, Harry Finke, Doug Haggerty, Felix Gyi, Charles Whitfield, and Tony Tommasello.

BALTIMORE METROPOLITAN PHARMACEUTICAL ASSOCIATION

President—Howard Schiff

The retirement of Charlie Spigelmire after 32 years of service as treasurer of the BMPA overshadows the accomplishments of the year. Charlie was a zealous watchdog over treasury and is largely responsible for its full coffers today. A luncheon honoring Charlie was held at the School of Pharmacy on the 5th of April. Dean Kinnard served as toastmaster and over 100 of Charlie's friends and admirers attended to hear the Senator lionized and presented with a special award.

Charlie's absence was acutely felt in the preparations for the BMPA's seventy-first Annual Banquet and Dance held again at the Blue Crest North in Baltimore. However, a large committee picked up the slack and sold the Man-of-the-Year raffle tickets as well as the Banquet tickets. The affair, with the appearance of Pharmacist-Delegate Don Elliott, the installation of Blue Cross pharmacy program supervisor, Stu Baltimore, as Honorary President, and a new band, was a social and financial success.

BMPA President Howard Schiff relates the recent activities of the local association to Vice Speaker Brian Sanderoff (left).

The BMPA was instrumental in getting the Pharmacy Network of Maryland off the ground. Max Richburg, from NARD's Rx Net National PSAO, along with Steve Miller of Georgia state PSAO, spoke at the BMPA meeting of October 7th. On the 9th of April, Lee Ahlstrom and Mel Rubin presented the MPhA program and then withstood an hour of questioning from approximately 150 pharmacists.

As usual, BMPA members were again active in the lobbying efforts in Annapolis and served selflessly for the profession. Hours were spent listening and attempting to convince legislators of the justice in our position. Their efforts, whether successful or not, lay a foundation for the programs of the future.

REPORT OF THE EMPLOYEE-EMPLOYER RELATIONS COMMITTEE

Chairperson—Dudley Demarest

The Employee-Employer Relations Committee met only twice in 1986–87 but was by no means inactive. The committee again published the Pharmacists Salary Survey in the Maryland Pharmacist and co-sponsored a ski weekend with the Alumni Association. The committee, along with the Young Pharmacists Caucas, requested the Board to hold evening meetings that would facilitate employee pharmacists' attendance.

Other ongoing projects of the committee include a Policy and Procedures Manual, a "Survival" kit for graduating pharmacy students, and compiling of a Chain Pharmacists' Benefits list.

The committee also discussed such issues as pharmacist work load, pharmacist to technician ratios, manpower statistics and their effect on salary distributions. The committee hopes to sponsor a "C.E. and Ski" weekend this winter.

The committee would also like to start an Employee-Employer "Forum" page in the Maryland Pharmacist and is looking for submissions. The committee is also looking for new members. The committee has many projects that need volunteer help to be accomplished and the committee just doesn't have the manpower. I ask all those owner-employers present to encourage your employees to consider working on the committee and I hope that many of you will wish to become involved in the committee's work and dialogue.

(More Reports Coming in the September issue)

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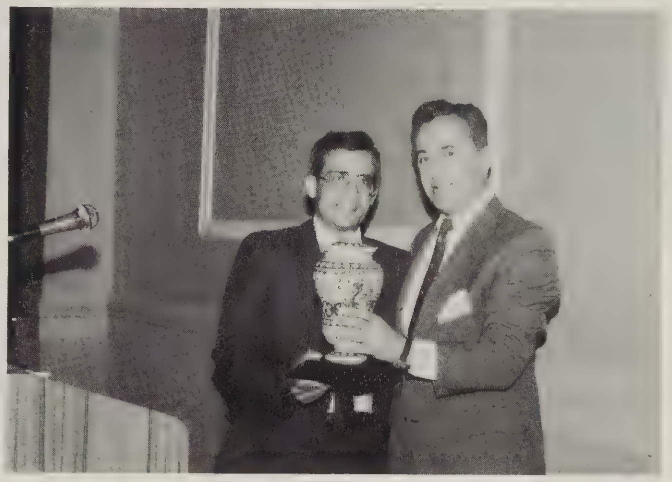
In a token of appreciation for many years of successful crab feasts as part of the convention, MPhA Presidet George C. Voxakis, (right) presents the volunteer firemen of the Berlin Maryland Firehall with a special gift. Maryland and Delaware Pharmacists and family agreed this years crab feast was one of the best.

John Paarlberg (right) of Marion Labs presents the first annual Young Pharmacist of the Year Award to Tom Williams (left) who is the president of the University of Maryland School of Pharmacy's Alumni Association.

Sheraton
Fontainebleau

William Skinner again delivered the Simon Solomon Seminar on Pharmacy Economics as part of the Convention Programming. The continuing education programs were co-sponsored by the Continuing Education Coordinating Council and C.E. certificates were mailed to attendees.



George C. Voxakis (left) receives the Squibb Past President's Award from company representative Jack Peters at the Convention Banquet.

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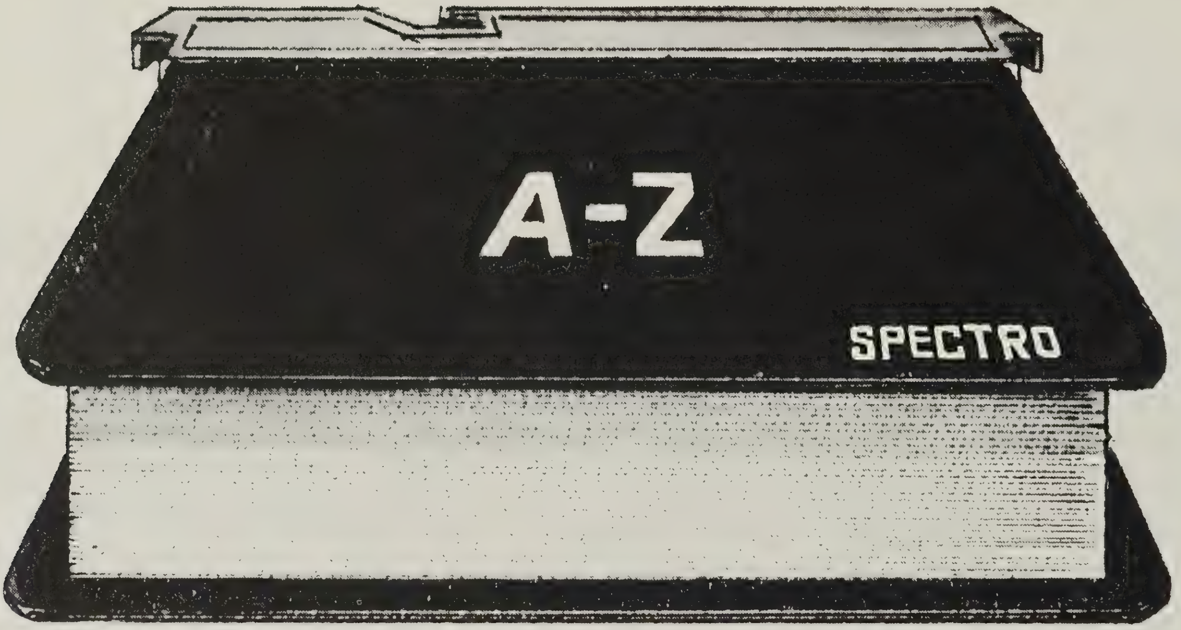

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

If individuals would like to receive a free copy of our Melanoma pamphlet, have them send a self-addressed, stamped envelope to:

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calendar

Oct 9–11—MSHP ANNUAL SEMINAR—WILLIAMSBURG, VA
Oct 18–23—NARD Convention
Oct 23–26—MPhA Trip to Nassau, Bahamas
Oct 23–25—Post NARD Convention side trip to San Francisco
Oct 25–Nov 1—APhA Midyear Meeting, Baltimore, MD
Jan 17–24 (88)—MPhA Trip to Curacao in the Caribbean

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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The interns tour the corporate museum at the Upjohn Visitor's Center. From left to right:
Allison L. Vordenbaumen, University of Texas at Austin
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Hedi M. Bloom, Wayne State University
Judith A. Shinogle, University of Kansas

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THE MARYLAND PHARMACIST

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OTC Mouth Washes, Gargles and Throat Sprays

—Thomas A. Gossel
—J. Richard Wuest

More Convention Coverage, Pictures and Reports

Lilly Digest Results for Community and Hospital Pharmacy

Outpatient Prescription Drug Coverage Under Medicare

—Peter P. Lamy

Commentary on Mail Order

—Jim Dickinson

THE MARYLAND PHARMACIST

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PRESIDENT'S MESSAGE

In todays health care marketplace where pharmacy is faced with such new challenges as, physician dispensing, and mail order drugs, it is more important than ever that we as pharmacists, not be preoccupied with these new forms of competition but should focus on what we as professionals do best, and that is to counsel and provide for the complete health care needs of the patient.

Todays consumers of health services are very well informed and realize the value and importance of the one-to-one personal relationship with the pharmacist. They realize the benefits that they can derive from the monitoring of medications for drug and drug-food interactions, screening for drug allergies, checking for prescribing errors, assuring patient compliance, especially with the elderly, and acting as an advisor to the patient on any number of drug and health related questions.

The fact that our patients, the consumers of health services, recognize and appreciate the quality services pharmacists have traditionally rendered is well documented by the gallup poll's high placement of our profession in regard to the performance and trust that consumers have shown other professionals.

In the near future, I see a new coalition forming between pharmacy and consumers to demand the continuation of the traditional drug delivery system and pharmacist-patient contact enjoyed by them for many years. This trend has already surfaced as some national consumer groups have voiced their opposition to physician dispensing, and the negative impact that mail order pharmacy, has on medication review and patient compliance by forcing patients to obtain some prescriptions through the mail while obtaining others at a local pharmacy.

Now is the time for we as pharmacists to accentuate the positive and to redouble our efforts to continue to provide the best drug therapy possible. It is my belief that consumers will not accept second best.

Lee A. Ahlstrom

President

CONTINUING EDUCATION FOR PHARMACISTS

Advising Consumers on OTC Mouthwashes, Gargles, and Throat Sprays

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. review conditions for which OTC mouthwashes, gargles, and throat sprays are indicated;
2. discuss appropriate OTC products to treat the conditions, listing actions, precautions, and adverse effects; and
3. provide consumer information that will assure the products are used correctly.

Objectives

At the conclusion of this lesson, participants will be able to:

1. identify common consumer complaints which may be treated with OTC mouthwashes, gargles and throat sprays;
2. compare OTC products and state their ingredients;
3. state the mechanism of action, uses, precautions and adverse effects associated with these products; and
4. demonstrate knowledge of specific consumer information for correct use of these products.

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There is a large variety of mouthwash, gargle, and throat spray products on the OTC market (Table 1). They are used to cleanse the mouth and upper throat area to impart a clean, refreshing feeling; sweeten the breath; aid in reduction of dental plaque; and treat irritated oral or pharyngeal tissues.

Each year Americans reportedly spend more than $500,000,000 on these products. Unfortunately, the medical and pharmaceutical literature contain little factual information about them or their uses in treating common disorders of the mouth and throat.

This article discusses mouthwashes, gargles, and throat sprays. It describes their actions and adverse reactions, and clarifies their usefulness in treating several common disorders of the oral cavity and pharyngeal area. It also provides relevant information for pharmacists to pass along to consumers.

Mouthwashes and Gargles

A **mouthwash** (mouthrinse, collutorium) is an aqueous solution for cleansing the mouth. The most commonly used one is a salt solution. Commercially available OTC mouthwash products contain pleasant tasting and smelling substances used to rinse or cleanse the oral cavity. They may or may not be flavored.

A **gargle** is a flavored and/or medicated solution used to bathe the posterior portion of the oral cavity, and help expel mucus from the throat. The terms mouthwash and gargle refer to the method by which they are used, rather than to specific ingredients or claimed benefits. The terms can be used interchangeably.

Gargling involves taking the fluid into the mouth and forcing expired air through it while the head is tilted backward. Gargles are intended for cleansing the throat, treating certain disease states, and relieving symptoms of sore throat.

Products that are intended solely to rinse, cleanse or refresh the mouth without making therapeutic claims are classed as cosmetics by FDA. When marketed as such, they have no labeling requirements for limiting their use. Products that are promoted for treatment of specific symptoms of disease must include limits of use in

TABLE 1

Representative OTC Mouthwashes/Sprays

Product (Mfr)	**Active Ingredients**
Bactalin (Whittaker General)	Cetylpyridinium
Cepacol (Merrell Dow)	Cetylpyridinium
Chloraseptic (Procter & Gamble)	Phenol
Listerine (Warner-Lambert)	Eucalyptol, thymol
Phenaseptic (Barre)	Phenol
Scope (Procter & Gamble)	Cetylpyridinium, domiphen
Viadent (Vipont Laboratories)	Sanguinarine

the labeling. Most commercial mouthwash solutions are used solely for cosmetic purposes.

The ideal mouthwash or gargle solution should be nonirritating, nonsensitizing, pleasant tasting and smelling, and non-toxic. It should be a stable solution that remains in contact with mucous membranes for the required time to exert claimed cosmetic or therapeutic effects, and not be absorbed by the mucous membranes. It should be easily rinsed from the mucous membranes when the desired effect has been obtained.

Halitosis

Halitosis is a loosely-defined term reportedly coined by Lister over a century ago. The term denotes foul or offensive breath or mouth odor. Bad breath, real or imagined, stimulates most people to take immediate corrective action. This frequently involves rinsing the mouth or gargling with an OTC mouthwash.

Bad breath *per se* is not a disease. Rather, it represents a sign or symptom of a local problem or systemic disorder. It generally disappears once the mouth has been cleansed, or offending systemic disorder has been corrected. If it persists, the individual should seek professional medical or dental consultation.

Approximately 90 percent of offensive mouth odors are of local origin, resulting from *extrinsic* sources such as odoriferous foods (onions, garlic, etc.), congeners in alcoholic beverages, or putrefactive reactions involving action of oral bacteria on entrapped food. Most of these reactions are readily controlled or eliminated by proper oral hygiene.

About 300 species of bacteria have been isolated from the mouth and throat area. There is no single species identified as the major source of oral malodor, but the fusobacterium and bacteroides species are usually responsible for most oral malodor in humans. However, neither species is pathogenic.

The cause of many oral odors is the volatile sulfur compounds such as hydrogen sulfide and methyl mercaptan produced by oral microbes during their metabolic processes. The major sites for this production are the crevices of the gums and cheeks, spaces between the teeth, tonsilar folds, and crypts of the tongue.

Oral odors intensify when the mouth is dry. Saliva is normally secreted at an approximate rate of 1500 ml per day. Saliva helps rinse food and putrefactive particles from the teeth and gums. It also reduces the activity of oral bacteria.

Almost everyone has unpleasant breath in the morning upon awakening. This is because saliva flow is diminished during sleep, and the tongue and cheeks are less active. It speaks well of the American advertising industry that has converted this normal physiological event into a half-billion dollar market.

Treatment. Mouth odors may be treated by masking, purging, antibacterial action, and neutralizing. **Masking** involves placing another (pleasant) odoriferous substance in the mouth. The effects of masking usually last 15 to 20 minutes.

Odors can be **purged** by actively rinsing with water, saline or mouthwash, or by brushing and/or flossing the teeth. Purging is effective because it physically dislodges accumulated volatile compounds, food debris, stagnant saliva, and bacteria.

Odors may also be destroyed by substances that have **antibacterial action** and reduce the number of odor-producing microbials. The duration of action of these agents is apparent when malodor is caused by bacterial action. These effects persist even after the action of purging or masking have dissipated. Agents that may be effective antimicrobials in one person may not be effective in another due to variations in the susceptibility of the microorganisms to the agent, and because the nature of oral flora differs from person to person.

Finally, the volatile sulfur compounds may be **neutralized.** Chemical neutralization provides a longer effect than purging or masking. This duration may be lengthened if action is accompanied by antibacterial activity.

OTC mouthwash products contain active ingredients that are bacteriostatic or bactericidal. Because they are swished around the mouth, they also aid in physically removing or purging food particles and odoriferous substances. And, because of their pleasant taste, they leave the mouth feeling fresh and clean.

The FDA Advisory Review Panel on OTC Oral Cavity Drug Products doubted the therapeutic effectiveness of gargling in treating disorders of the throat. The panel reported that medication could not reach the posterior pharyngeal wall or posterior pillars of the throat unless it was swallowed. Therefore, gargled solutions normally do not come in contact with diseased throat tissues. However, the forceful expulsion of air from the throat during gargling could help expel mucus from pharyngeal structures. Throat sprays are probably more effective delivery systems for administering drugs to pharyngeal tissues.

Some solutions used for gargling contain detergents. These lower the surface tension of the fluid, enabling it to penetrate into areas such as the convoluted areas of the tongue and throat which are not readily permeable to water.

Antimicrobial mouthwashes must be used repeatedly, at least every 3 to 4 hours, if a prolonged breath refreshing action is desired. However, some nonpathogenic microbes residing in the mouth actually contribute to oral cleansing. If these organisms are destroyed along with the odor-producing ones, increased mouth odor may actually result.

Continued use of mouthwashes may disguise offensive breath odors due to an underlying disorder. The condition may worsen over time, and needed professional help will not be sought until the condition is well advanced.

Dental Plaque

Dental plaque is a soft, sticky, adhering mass that forms on the surfaces of tooth enamel. Its composition varies, but generally consists of bacteria and bacterial by-products, carbohydrates, sloughed epithelial cells, salivary components, and leukocytes that are enmeshed in a gel-like substance.

Plaque is not a disease *per se*, and its presence does not denote that tooth and gum diseases will occur.

Plaque irritates teeth and gums, and is the leading etiologic cause of caries formation and periodontal (gum) disease. This in turn contributes to tooth loss.

Plaque begins to form within an hour after eating. If it is not removed, it calcifies within 24 hours to form **tartar.** Plaque is not easily removed by rinsing the mouth; it is best removed by brushing and/or flossing the teeth. Tartar, once formed, cannot be easily removed by either brushing or flossing.

Some mouthwash products have been shown to aid in reduction of dental plaque formation. By helping to reduce development of dental plaque, mouthwashes can significantly lengthen the time before periodontal disease and tooth loss occur.

A frequently asked question is whether a good water rinse is just as effective as mouthwash in reducing plaque. In a study to test this, subjects rinsed their mouth with water or Cepacol™. Microscopic examination of the oral tissues revealed that both water and mouthwash rinses mechanically removed debris from teeth and gums. But, the water rinse produced only a slight (17 percent) depression in oral microbial population. The mouthwash product effected an almost complete (96 percent) reduction in bacterial count. Furthermore, the antimicrobial mouthwash product exhibited a high substantivity (ability to adhere to the oral tissues and lengthen the activity). Direct evidence showed that it persisted for as long as four hours after rinsing.

Currently marketed mouthwash products which have demonstrated clinical utility in controlling plaque include those that contain cetylpyridinium chloride, domiphen bromide, sanguinarine, and/or a mixture of volatile oils. Other OTC mouthwash products also claim to possess some degree of anti-plaque activity. While this may eventually be substantiated, there are insufficient data at present to generally support such claims.

Cetylpyridinium Chloride. This popular quaternary ammonium compound (QAC) was first shown in 1916 to possess antibacterial activity, and was marketed for this purpose in 1942. It is bacteriostatic and bactericidal against many gram-positive and gram-negative bacteria, and some fungi.

The exact mechanism by which cetylpyridinium chloride and other QACs exert antimicrobial activity is not known. A number have been suggested. For example, they may disrupt the microbial cell membrane and allow its cytoplasm, enzymes or other substances to diffuse out. They may dissolve the protective lipid films in the microbial cell membranes since they are lipophilic. They may denature certain proteins on the cell surface. Or, they may inactivate microbial intracellular enzymes or interfere with the activity of enzymes involved in transporting chemicals across cell membranes. Activity most likely results from a combination of mechanisms.

Cetylpyridinium chloride is reportedly the most potent QAC against *Streptococcus mutans* and *S. sanguis*. Both organisms cause dental plaque formation and oral malodors.

Domiphen Bromide. Another QAC, domiphen bromide, also possesses antibacterial action and may act similarly to cetylpyridinium chloride. While some studies suggest that domiphen is active as an oral antibacterial, many of these have been uncontrolled, and the responses objective rather than scientific.

Sanguinarine. This has been used as an expectorant in cough syrup products for over 150 years. More recently, some reports have suggested that sanguinarine has effectiveness against certain aerobic and anaerobic bacteria, including some of those that cause dental plaque. The precise mechanism of action and overall clinical significance are unknown at present.

Volatile Oils. Volatile oils (e.g., eucalyptol, thymol) have been used empirically as antimicrobials for many years, even though there are few data to support this use. They penetrate bacterial cell walls and interfere with their metabolism. Volatile oils also impart a burning taste or stinging sensation to the mouth, although some of them cause a sense of coolness first. This results in reflex salivation which, in turn, aids in purging of bacteria and food particles. If these solutions are left in the mouth, they may cause uncomfortable irritation and discomfort.

Sore Throat

Sore throat is one of the most common afflictions in the U.S. Approximately 100 million Americans report at least one episode each year; many experience multiple sore throats yearly.

Sore throat is a symptom with many causes. It generally refers to pain, discomfort or burning of pharyngeal tissues, especially on swallowing. Unfortunately, it is a nonspecific term, and trying to relate a consumer's subjective complaint of "mild," "minor," or "severe" sore throat to a specific cause is difficult.

Sore throat may represent a minor irritation of local origin, such as from swallowing hot or irritating foods, or accumulating thick, viscous secretions from nasal or pharyngeal tissues (i.e., postnasal drip). Sore throat may herald the onset of serious infections such as candidiasis, measles, chicken pox, pneumonia, or lethal blood dyscrasias such as aplastic anemia and agranulocytosis. It may even represent an early manifestation of acute leukemia.

Sore throat is commonly self-treated with OTC gargles or sprays (as discussed earlier), or lozenges.

Phenol. Phenol (carbolic acid) has been used as an antimicrobial since Lister demonstrated its effectiveness in 1857. Its current use in OTC sore throat products is restricted to its local anesthetic action. In therapeutic concentration, phenol penetrates the sensory nerve endings to exert an action similar to other local anesthetics/analgesics.

Concentrations less than 1.5 percent in aqueous solution are safe when used as directed. Greater concentrations are irritating to oral tissues.

Consumer Information

For optimal activity, mouthwashes, gargles, and throat sprays must be used correctly. For best results, mouthwashes should be swished around the mouth and forced against the teeth for approximately one minute, then expectorated. Gargles are "gargled" for as

TABLE 2

Consumer Advice

General

- Stop using this product and consult a doctor if oral irritation persists or increases, or if a rash appears on your skin.
- Do not use this product without the advice of a doctor or dentist if your mouth is highly irritated or has ulcers in it.
- Try to avoid swallowing this product.
- Keep this product out of the reach of children. If a child swallows more than a "swallow" (about 5 ml), contact a doctor.
- Using this product for improving bad breath is not a substitute for good oral hygiene and regular dental check-ups.

Plaque Control

- Rinse your mouth with this product for about 30 seconds, twice daily. Swish it through your mouth and around all the teeth. Expectorate it when finished. Do not eat, drink, or smoke for 30 minutes after rinsing your mouth.
- This product's effectiveness will be most pronounced if rinsing is done immediately after brushing and/or flossing your teeth.
- Using a mouthwash product to control plaque is not a substitute for regular brushing and flossing, or for regularly scheduled dental examinations.
- Stop using this product if it causes irritation to the tissues of your mouth. If irritation persists, consult a doctor or dentist.

Sore Throat

- Sore throat that is severe or persistent, accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.
- Do not use this product more than 2 days or give it to children under 3 years of age unless directed by a doctor.

long as is comfortable, then expectorated. Throat sprays should be applied as far back in the throat as possible. The user should refrain from swallowing for as long as possible. Other liquid or food should not be placed in the mouth immediately after using these products. Table 2 contains important information for consumers.

Dental plaque control is an ongoing process. To minimize plaque formation, people must brush and/or floss regularly, ideally after each meal and at bedtime. Mouthwashes are not a substitute for a conscientious program of toothbrushing and flossing. Used in conjunction with these procedures, mouthwashes help in plaque control, as long as the person complies with the program.

Individuals complaining of sore throat should be checked for other symptoms. If congestion is present, an OTC oral or topical decongestant can be recommended. Runny nose and eyes, fever, and G.I. disturbances may signal the presence of a viral infection. A patchy exudate over the pharyngeal mucosa often suggests a bacterial or fungal infection, especially when the voice is "husky" or "thick." These persons should be instructed to consult a physician.

Bad breath that persists, or a sore throat that continues for several days must be evaluated by a dentist or physician. These may signal the presence of a serious medical problem.

Mouth ulcers may be a symptom of malignant oral cancers. Any ulceration in the mouth, no matter how small or asymptomatic, that persists for more than several weeks should be investigated by a physician.

The therapeutic effectiveness of mouthwashes, gargles and throat sprays is due to local actions on the mucous membranes of the mouth and throat. Absorption through the mucosa of the mouth and pharynx occurs readily, and adverse systemic effects can occur. Rinsing or gargling is generally so brief in duration that contact with mucous membranes is minimal. Medication remains in the mouth after spraying the throat, but usually in such low concentration that it is not a problem.

Mouthwashes are safe when used as directed. But OTC mouthwash products contain ethanol in concentrations of 14 to 30 percent to enhance solubility of the other ingredients. A single bottle of mouthwash can, therefore, contain a lethal quantity of alcohol if the contents are swallowed by a child. Serious poisonings have been documented. Since they are not packaged in child-resistant containers, consumers should keep these pleasantly tasting and smelling products out of the reach of children.

October is "Talk About Prescriptions" Month sponsored by the MPhA and NCPIE. Reproduce the flyer below and on page 25 to distribute to your patients.

TALK ABOUT PRESCRIPTIONS

MEDICINE:

Before you take it, Talk about it

Ask your health care professionals these questions about your prescription medicines.

1. What is the name of the drug and what is it supposed to do?
2. How and when do I take it – and for how long?
3. What foods, drinks, other medicines, or activities should I avoid while taking this drug?
4. Are there any side effects, and what do I do if they occur?
5. Is there any written information available about the drug?

MP

NATIONAL
COUNCIL ON
PATIENT
INFORMATION AND
EDUCATION

22,000 Items. Now that's healthy!

You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

YOUR DIRECT SPECTRO REPS ARE:

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THE HEALTH CARE COMPANY

SPECTRO INDUSTRIES

YOU WANT GREATER RECOGNITION FOR PHARMACY.

SO DO WE.

The future of pharmacy will be shaped by the many bright, well-trained young pharmacists entering the work force today. Their high standards of practice will carry the profession well into the next century.

At Marion, we believe in recognizing the best of these young pharmacists and their accomplishments as an example for others to follow. That's why we sponsor our "Distinguished Young Pharmacist Award," presented annually to a young pharmacist in each state for individual excellence and outstanding contributions in state pharmacy association activities, community affairs, and in professional practice.

In Maryland, this year's Distinguished Young Pharmacist Award goes to Thomas G. Williams of Towson. Congratulations!

We're confident that this year's distinguished young pharmacists will become the leaders who shape pharmacy's future well into the next century. And that's a future Marion believes is worth looking forward to!

1987
Distinguished Young Pharmacist
In recognition of
individual excellence and
outstanding service to the
profession of pharmacy.
Sponsored by Marion Laboratories, Inc.

Service to Pharmacy

PHARMACEUTICAL DIVISION
MARION
LABORATORIES, INC.
KANSAS CITY, MO 64137

1680K7

Convention reports

PRESCRIPTION NETWORK OF MARYLAND

President—Lee Ahlstrom

At the present time there are more than 700 HMOs and more than 500 PPOs nationally that serve 54 million patients. Their ranks are expected to swell to 80 to 100 million patients by 1990. Many of these organizations are seeking cost effective pharmaceutical service with accessibility to their membership through a good geographic distribution of pharmacy providers. They want to deal with one administrative contract and also realize that drug utilization review is an important factor in cost-containment.

An independent pharmacy or chain alone can't provide the geographical coverage to service these types of organizations. These are some of the reasons leading to the establishment of the Prescription Network of Maryland (PNM), the for-profit subsidiary of the Maryland Pharmacists Association. Approximately 400 stores, both chain and independent, have joined PNM.

Health Services Plus (HSP), a firm experienced in negotiating contracts in a number of states nationwide, has been retained on a consulting basis to assist in soliciting and negotiating contracts of PNM. We are currently negotiating with several large insurance companies and HMOs for new prescription business for our members. Since almost all of the work load is being performed on a volunteer basis by the members of the PNM board, in order for PNM to be successful the most important factor is you, the practicing pharmacist. We need your help in the marketing of our network. To assist you in this, promotional materials are being developed explaining the many options and services available through PNM. You should have already received summary information sheets that briefly describe PNM and "lead sheets" for your use to help us recruit and develop potential network contracts. Additional copies are also available from the office. This is *your* opportunity to help us recover business lost to mail order, exclusive contracts, locked in HMOs and other cost containment schemes which have taken away your patients. PNM and HSP will follow up on any leads generated by member pharmacies. Please complete the "lead sheet" form and mail it to the office as soon as possible. The extent of our success is in your own hands. Let's all work to make this the best provider network possible.

NEWSLETTER COMMITTEE REPORT

Chairman—Melvin Rubin

The newsletter has continued to attempt to bring the most up to date and informational news to the members as well as items of general interest. Judging from comments and requests to have information included it apparently is widely read and accepted. For about the tenth straight year, I will repeat, the Newsletter can be made better if we have your input. In effect, with only Dave Banta and myself providing stories, except for specific requests for publicity, and this leaves out news which should be shared. It would be to everyone's advantage if local groups and specialty groups would appoint someone to contribute monthly.

Prescription Network of Maryland President Lee Ahlstrom presents the PSAO's first report to the Convention.

Continuing Education Coordinating Council

David A. Banta, Secretary

The Continuing Education Coordinating Council is a tripartite effort of the MPhA, the Maryland Society for Hospital Pharmacists and the University of Maryland School of Pharmacy. Volunteers from each of these three organizations attempt to plan and execute at least four major seminars for pharmacists on an annual basis. The Council is an approved provider of the American Council on Pharmaceutical Education and was recently renewed for an additional three year period.

The MPhA staff provides support to the work of the Council and routinely provides, bookkeeping, certificates, registration, graphic design, arranges printing, etc. Volunteers who serve on the Council and who Chair Council seminars find the effort personally and professionally rewarding.

Over the past year the CECC has sponsored or cosponsored a greater number of programs than in the past. In addition, attendance seems to be on the rise, perhaps in part to the impending implementation of the requirement for mandatory continuing education for pharmacist relicensure.

At last years MPhA convention, the CECC co-sponsored the outstanding continuing education program on "The Elderly and Their Vitamins: Maybe They're Right." The CECC also co-sponsored the MSHP's "Pharmatrends" program as part of the twenty-first annual Hospital Pharmacy Seminar.

On November 9, 1986, the CECC and the American Cancer Society presented a seminar on "The Pharmacists Role in Cancer Prevention and Early Diagnosis." In January, 1987, the MPhA's group travel trip to Hawaii featured a CECC sponsored program on "Effect Pharmacy Management." The MPhA's Mid Year Meeting also had a CECC sponsored program on the popular "Update on New Drugs and Trends in Pharmacy" by Gossel and Wuest.

In March, 1987, the CECC sponsored Seminar on

"Airway Disease" was especially popular as was the April Seminar on "Advances in Cardiovascular Therapy," which also served as the AZO Berman Seminar. The most impressive turnout for any program over this past year was evident at the May 17th CECC Seminar on "Arthritis Assessment."

The CECC Subcommittee on Planning is meeting now to plan the programs for the 1987–88 program cycle. I would urge anyone interested to contact us in the MPhA office to volunteer to serve on this extremely important committee. Thank you.

MEDICAID COMMITTEE REPORT

Chairman—Mark Levi

I am pleased to report that there will be a 25 cent increase in the professional fee for Medical Assistance prescriptions. This increase did not come without great effort by the leadership of our association. What was originally proposed as a discount off of AWP of up to 12% with a 50 cent increase was turned around to a fee increase of 25 cents. The IDC program is expanding with every increased savings to the state of Maryland. We are still trying to claim part of that savings into an additional fee. An incentive to fill prescriptions with generic equivalent medication that is not on the IDC program is a proposal that is brought up each year also. Special packaging that will aid in compliance has also been put on past agendas and will be put on future agendas. Finally, there will be a change in the hard copy billing of medicaid prescriptions, but as far as I know there will be no change in computer format billings.

We must continue to maintain a high profile for our profession in the local community that we live in as well as in Annapolis if we are to have more victories than defeats.

TRAVEL AND CONVENTION REPORT

Chairman—Elwin Alpern

Our trip to Hawaii, January 14, 1986 was most successful. We visited 2 Islands and the trip lasted 12 days. David Banta presented a program for 7 Continuing Education Credits on Effective Pharmacy Management. Our meetings were 8 AM till 11 AM and the rest of the day was for pleasure.

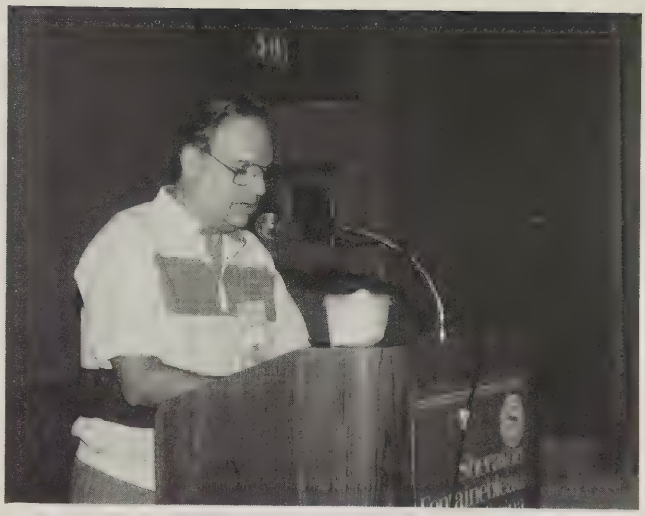
Our 1986 Convention at the Sheraton in Ocean City with a attendance of 300 people. There were 38 paid exhibitors in 1986 who paid fees of $10,800.00 and contributions of $4,875.00. Our registration fees accounted to $16,946.50. The net profit was an amazing $13,544.22.

We have arranged 2 trips for our members for October 1987:

October 23–26—4 days
The Cable Beach Hotel and Casino in Nassau, Bahamas. Roundtrip air from BWI. 3 Nights accommodations, transfers and baggage handling in Nassau.

$419.00 per person, double occupancy. Call Towson Travel—Group Department 823-7780 in Baltimore or 737-1064 in Washington for details.

October 23–25—Post Convention Trip
Sir Francis Drake Hotel in San Francisco. 2 Nights accommodations, transfers and baggage handling in San Francisco.



Convention and Trips Committee Chairman Elwin Alpern reports on a successful year.

$121.00 per person, double occupancy. Stopovers in San Francisco can be added to your Las Vegas airfare for a small additional charge. Contact Towson Travel—Group Department 823-7780 in Baltimore or 737-1064 in Washington for details.

I want to thank David Banta and Mayer Handelman for their help during the last year. A special thanks to Beverly and Mary Ann.

Thank you.

SPEAKER OF THE HOUSE REPORT

Chairperson—Geraldine Epley

It has been an honor to serve as Speaker of the House this past year, and to sit on the Board of Trustees. I deeply regret that another professional obligation has prevented me from attending the 105th Maryland Pharmacist Convention. The annual convention has been an important milestone for me, both professionally and personally for a number of years, and my thoughts are in Ocean City with all of you.

This past February, the mid-year meeting was held at the Annapolis Hilton with a capacity crowd of over 110 attending. Thomas Gossell and J. Richard Wuest reviewed the new drug products during the morning session. At lunch, Grady Dale Ph.D. presided over the ceremony honoring scholarship program participants from the University of Maryland School of Pharmacy. After lunch, Pat Hawk from Blue Cross/Blue Shield talked about "What's Ahead for the BC/BS Prescription Drug Program." Then a short House of Delegates meeting followed during which Executive Director Dave Banta briefed the attendees on the legislative package before the General Assembly in Annapolis. The Nominating Committee gave a report on officers, trustees, and the Board of Pharmacy.

I'd like to thank all the members who volunteered their valuable time and effort to make this a successful year for the Maryland Pharmacists Association. The DUR program has been implemented, new insurance programs are being investigated, and the various committees have made progress in such areas as continuing education and pharmacist rehabilitation. This coming year, physicians dispensing for profit will be of primary concern to all of us. The united support of the membership is crucial as we prepare to enter the next legislative session, so that we can achieve our common goals.

ALUMNI ASSOCIATION REPORT

President—Thomas G. Williams

This has been a very exciting year for the Alumni Association. We began earlier than usual, in July, to participate in the discussions regarding the Pharm.D. decision. In October we sponsored the annual dinner meeting. The guest speaker was a local celebrity, Mr. Ted Venetoulis. Next, we co-sponsored a weekend ski trip with the Maryland Pharmacists Association. Also in January, the executive committee voted to join the University Club, an alumni-related club located on the UMAB campus. Following this, in March, several members of the executive committee participated with various other alumni in the School of Pharmacy's Phon-a-thon. Finally, in May, the association's banquet, in honor of the graduating seniors and the 50-year graduates, was held. At this banquet also was the installation of officers for the 1987–88 year.

We look forward to an even more exciting year this year.

Tom Williams, President of the Alumni Association delivers his report to the House of Delegates. Tom also received the Young Pharmacist of the Year Award at the Banquet.

Congratulation and Welcome to the Profession of Pharmacy —U of M Pharmacy Grads

THE CLASS OF 1987

BACHELOR OF SCIENCE IN PHARMACY

IRENE BALODEMAS
KAREN LYNN BORAM
PATRICK EDWARD BURKE
CAMILLE YVETTE BUTLER
MATTHEW R. CARROLL
SUE ELLEN CHERRY
SIMONNE MARIE DEVAUX
PENELOPE DIAMANDARAS
ANITTA CHAPMAN DUDLEY
DONNA MARIE EBY
GERARD V. EWANCIO
SCOTT WOODWARD FISHER
MARY BETH FRIEDEL
MARGARET EMILY GERAGHTY
DONNA MARIE GILETA-CLECKNER
LEE JENNINGS GRIER
ANITA GUPTA
KAREN ANITA HARTONG
JOAN CAROLE HASTINGS
SCOTT ALTEN HISEY
JOHN DAVID HOELSCHER, III
FOREST SCHUYLER HOWELL
ALAN IRVIN HUBER
MARK TILGHMAN JOHNSON
GAIL ANNE KADRON
NAYRI N. KHAIRALLA
MARY ELAINE KOWALCZYK
MARY E. KREMZNER
HANNA BONSUN KU
THOMAS PHILLIP LAMARTINA
KATHLEEN DAWN LAUER
JAMIE SUE LEVY
BRUCE DAVID MARQUETTE
JUDY S. McKAY
LISA ANN MILLER
VICKI L. MILLER*
JAMES R. MITCHELL
DONNA MONDELL
CYNTHIA L. MOSTYN
MEGAN GRACE MURPHY
HOO JA OH
JEAN MARIE OSMAN
SALISH THAKORBHAI PATEL
TIMIR J. PATEL
VINCENT EARL PEARSON
CHALIT PIRUNJAREON
PHILIP GREGORY PRICE
MARY ELIZABETH ROBERTS
RHONDA LEIGH SCHEURER ROBINSON
LAURA ELLEN SAMPSON
LINDA GAYLE SCHULTZ
JEAN ANN SCHUMAN
LaMONT CHARLES SMITH
SUSAN THERESA SMITH
ANN MARIE SPELLMAN
LARRY EUGENE STEVENSON
MARGARET LETITIA STEWART
ANDREA L. STOLARIK
BRIAN C. SUMLIN
JOANNE EVELYN TILLEY
LEILA RAMONA VALENCIA
LEO CHARLES WEBER
KERA JOAN WITCHER
ROBERT NEAL ZUNIKOFF

* August 1987

DOCTOR OF PHARMACY

KATHRIN ELISABETH CHOATE
MONA LYNN GOLD
BETSAIDA HAYDEE GUZMAN
EDMUND ERDVILAS KASAITIS
CYNTHIA LYNN LACIVITA
BONNIE DARLENE PURDY
CYNTHIA LYNN SENS
JAY DANA SHERR

NECROLOGY REPORT
Deceased Alumni, Since May 1986
University of Maryland Pharmacy Alumni

NAME	DEGREE	YEAR
Manuel Abramowitz	Ph.G.	1933
Truman L. Anderson	Ph.G.	1933
Charles F. Bruening	M.S.	1935
Robert L. Buck	B.S.	1952
Ralph Colvin	B.S.	1938
Michael B. Corcoran	B.S.	1979
Abe Danoff	B.S.	1934
David Feldman	Ph.G.	1931
William T. Foley	Ph.G.	1930
Charles S. Friedman	B.S.	1937
Samuel W. Goldstein	Ph.G.	1926
	B.S.	1929
	M.S.	1931
	Ph.D.	1935
Jerry Gotkin	B.S.	1951
Jaye J. Grollman	Ph.G.	1931
	M.D.	1936
John F. Hershner	Ph.G.	1926
Reuben Kahn	B.S.	1941
Frank C. Kalivoda	B.S.	1975
Edward E. Lyden	B.S.	1953
Ben H. Macks	Ph.G.	1933
Alexander M. Mayer	B.S.	1937
Harry R. Meagher	Ph.G.	1926
John C. Michel	Ph.G.	1931
Albert M. Newman	B.S.	1951
Alexander Ogurick	B.S.	1936
Carroll M. Price	Ph.G.	1926
Robert Rejonis	B.S.	1971
Sally W. Siegel	B.S.	1949
Louis Vogel	Ph.G.	1933
William E. Waples	Ph.G.	1918

Submitted by Margaret Beatty/Leon Weiner
4/30/87

Kathy Gauthier served as Chairman of the Membership Committee. She was also elected and installed as a member of the Board of Trustees.

MARYLAND PHARMACISTS ASSOCIATION MEMBERSHIP COMPARISON REPORT
June 87

	1983	1984	1985	1986	1987
TOTAL MEMBERS TO DATE:	938	1007	1023	1044	1019
NEW MEMBERS TO DATE:	104	96	79	67	51

COMPARISON: 1985 to 1986

MEMBERS TO DATE:	−25
New Members to date:	−16

	1983	1984	1985	1986	1987	COMPARISON 86–87
BREAKDOWN:						
OWNER-MANAGER	185	193	210	186	176	−10
NON-OWNER	422	451	451	515	511	− 4
PLEDGE—1ST YEAR	56	61	52	45	35	−10
2ND YEAR	32	30	40	34	23	−11
HOSPITAL	33	27	33	24	30	+ 6
GRADUATE	2	6	9	3	4	+ 1
RETIRED	89	116	113	120	116	− 4
NON-RESIDENT	80	85	82	70	79	+ 9
JOINT	7	7	7	6	6	—
ASSOCIATE	32	31	29	41	39	− 2
Comparison:	938	1007	1023	1044	1019	−25

The statistics show that we are a little behind last years figures. A half year membership promotion is expected to correct this problem and hopefully pass last years figures. The report shows that we are making steady progress in membership every year, and with the continued work of the Membership Committee this growth should continue.

I would like to extend my fullest appreciation to the Membership Committee, David Banta, and Beverly Litsinger for their time and efforts this year.

Kathy Gauthier
Chairperson

Meet the newest chapter in our history of excellence.

For ten weeks, they skimmed the pages of a century's experience in the pharmaceutical industry. And they learned, about manufacturing, about research, quality control and marketing. But they didn't stop there. As members of Upjohn's 14th annual National Pharmaceutical Council-Student American Pharmaceutical Association (NPC-Student APhA) Internship Program, they went on to begin a chapter of their own. And quite frankly, we were impressed.

Through their eyes, we got an exciting glimpse into the future. And renewed assurance that pharmacy's next chapter will be promising indeed. **Upjohn**

The interns tour the corporate museum at the Upjohn Visitor's Center. From left to right:
Allison L. Vordenbaumen, University of Texas at Austin
Mark B. Boeckmann, University of Ilinois at Chicago
Hedi M. Bloom, Wayne State University
Judith A. Shinogle, University of Kansas

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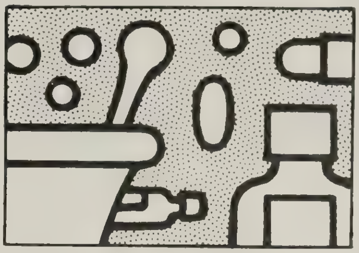
MPhA Continues A New Member Service and Journal Feature

The patient education aid on the right is part of a series presented by the MPhA Public Affairs Committee. It is intended to assist the pharmacist in providing useful health information to his or her patients. If this sort of material is valuable, the committee hopes to prepare such aids on a continuing basis. Since the effort at right represents a "pilot test" it would be most helpful if members would let us know whether they are able to utilize such material, suggest future topics, or suggest improvements in content or format. Please address your comments to MPhA, 650 W. Lombard St., Baltimore, MD. 21201.

The aid is designed for distribution to patients as a "package stuffer" or for mailing as an enclosure with monthly statements. Where possible, and for best results, review the material with your patients, emphasizing items of individualized importance.

To remove the patient aid, simply cut along the dotted line. The aid may be reproduced in quantity by photocopier or inexpensive offset printing. If you want to add your name, address, or other information, place such information so that it covers the artwork in the upper right hand corner.

Things You Should Know FOR YOUR GOOD HEALTH



Insect Stings and Bites

The summer season, besides bringing warm weather and fun in the sun, is often accompanied by insect stings and bites. Medical literature is filled with articles on allergic reactions to insect stings and bites. In extreme cases people have died from the venom of stinging insects. Although accurate statistics on the number of Americans who die annually due to insect bites and stings are not available, approximately 1.5 million patients are at high risk due to severe allergy to venom. This is generally a reaction of the body, know as anaphylaxis, due to an intense sensitization to the venom. When death results in these cases, it is from respiratory obstruction caused by swelling of the vocal cords or severe constriction and congestion of the bronchial tubes, and anaphylactic shock.

An insect sting or bite is a skin injury caused by penetration of the stinger or the biting organ of the insect. Some of the more common stinging insects include honeybees, wasps, hornets and yellow jackets. These small insects have a venom that is as potent as that of snakes. Death by an insect sting may happen within minutes.

In non-sensitive individuals a bee sting causes nothing more than a localized painful swelling with redness and itching. However if several stings occur at one time, enough venom can be absorbed in the bloodstream to make the victim quite ill, with severe hives or a generalized swelling of all the tissues. A honeybee sinks its barbed stinger into the skin and is unable to withdraw it. Wasps', hornets' and yellow jackets' stinging mechanism resembles that of the honeybee, with the main difference being that their stingers are not barbed. The stingers can be withdrawn easily, permitting repeated stings by the same insect.

The first line of treatment for an insect sting is to remove the stinger, assuming the victim is not in severe distress. Using a sharp object such as a knife blade or fingernail, scrape the stinger gently. Do not try to grasp the stinger with fingernails or tweezers, since this simply forces the remaining venom into the skin.

When the stinger has been removed, local treatment of the affected area may be helpful to decrease the swelling and pain. Prompt application of ice packs to the sting site helps slow down the absorption of the venom into the bloodstream and reduce itching, swelling and pain. Application of strong Epsom salt soaks may also provide relief and help to reduce the swelling.

Many non-prescription (over the counter) products are available for topical symptomatic relief. These products contain one or more ingredients such as antihistamines, anti-inflammatory agents (including hydrocortisone), external analgesics (pain killers), and antibacterials (to protect against infection). ASK YOUR PHARMACIST TO recommend the best non-prescription medication to keep in your first aid kit. Remember, precaution is the best medicine.

© SPEA

Practice Management

Lilly Digest Survey Results for Community and Hospital Pharmacy Practice

This preliminary *Lilly Digest* report is based on the 1986 operating statistics of 997 independent community pharmacies. Although the cost of goods sold increased, it was offset by a reduced total expense figure, which resulted in net profit remaining unchanged from the previous year at 2.8% of sales. Comparison of *Lilly Digest* figures for 1985 with 1986 income and expense figures shows that . . .

> Sales totaled over $661,000, an 11% gain of almost $68,000 over 1985's figure. This rate of increase is somewhat higher than the average annual growth of 10.5% observed during the past decade. Prescription sales increased over 13% from 1985 figure and significantly outpaced the 8% increase noted in other sales. Prescription sales accounted for 63.3% of the average pharmacy's volume.
>
> Gross margin declined to 32.1% of sales (down from 32.6% in 1985), the lowest gross margin level since 1942. Total expenses decreased to 29.3% of sales—down from 29.8% the previous year. Net profit before taxes was 2.8% of sales, unchanged from the prior year.

Although total expenses fell percentagewise, there was an increase in dollars of over $17,000, or 9.6% higher than the 1985 figure. Proprietor's salary was higher in dollars (up about $3,300) but decreased slightly to 5.8% of sales. Similarly, employees' wages rose dollarwise but remained unchanged at 10.2% of total volume. The percentage figures for employees' wages for 1986 as well as 1985 were the lowest since 1954.

Rent declined slightly to 2.3% of sales, but was almost $1,300, or 9% higher for the year. Miscellaneous operating costs rose just over $5,400, an 8% increase. However, during 1986 these miscellaneous costs comprised a smaller share (11%) of the sales dollar. This was the result of a percentagewise decline, in advertising, delivery, and interest expenses, which more than offset the increase in insurance and miscellaneous expenses.

Net profit before taxes showed an increase of over $1,600—up almost 10% from 1985. In dollars, total income (proprietor's salary plus net profit before taxes) increased 9.6% but declined slightly as a percent of sales from 8.7 to 8.6%.

Prescription and nonprescription inventories required more dollars during 1986; however, both declined as a percent of sales—from 10.5 to 10.4% and from 22.0 to 20.8% respectively. The sales productivity of the prescription inventory moved up to $9.64 per stock dollar (15 cents higher than in 1985), whereas the productivity of other merchandise rose to $4.80, up 26 cents from the previous year.

The average number of new prescriptions increased by 644 to 50.1% of total prescriptions dispensed (up 4.6% from 1985). Renewed prescriptions were higher by 436 (up 3.1%) over the previous year's figure and accounted for 49.9% of total prescriptions dispensed. A record high of 29,427 prescriptions were dispensed during 1986 (up almost 4%). The average prescription charge was $14.23 during 1986, an increase of $1.19, over the 1985 figure of $13.04.

Merchandise selling space in the average independent community pharmacy was over 2,800 square feet during 1986. Sales per square foot of floor area advanced $9.27 from the year earlier to $229.25. The hours of operation in the typical *Lilly Digest* pharmacy declined slightly during 1986 to 61 hours per week.

The annual *Lilly Digest* will be completed and distributed during September of this year.

Hospital Pharmacy Survey Results

This preview of 1986 hospital pharmacy operations was abstracted from the 1987 edition of the *Lilly Hospital Pharmacy Survey*. The new *Survey* is based on information received from 2,167 hospital pharmacies and is the tenth consecutive edition prepared by Eli Lilly and Company.

Table 1 shows that in 1986 the average hospital had 235 beds—down almost 4% from the previous year. Census again declined during 1986. Census has fallen consistently since 1982, and is almost 15 percentage points below the average annual census rate of close to 73% observed during the 1975 through 1981 period. Admissions during 1986 were about 2% lower than the previous year.

The average length of hospital stay declined from 6.2 days last year to 6.0 days in 1986, the shortest period of patient stay ever recorded in the Lilly *Survey*. The largest segment of hospitals reporting to the *Survey* continues to be private, nonprofit, general hospitals.

The number of hours the central pharmacy was open as well as the hours worked by pharmacists and technicians declined slightly during 1986, although support personnel hours remained virtually unchanged. The total hours worked by the overall pharmacy department staff fell over 3%, while the central pharmacy was open 3% fewer hours. Three hours of pharmacist time were required for each hour the central pharmacy was open during 1986—slightly less than that recorded last year. The ratio of hours worked by technicians to hours open was unchanged at 2.8. Hours worked by support personnel for each hour open increased slightly from 1.1 to 1.2 during 1986.

For the third time in as many years, the dollar value of inventory declined when compared with the previous year's figure. In addition, purchases were 2% higher, with the result that the estimated inventory turnover rate increased from 8.5 to 8.7 times. However, on a per-occupied-bed basis, inventory and purchases figures were about 5% and 8% higher respectively than in 1985.

Comparison of inventory and purchases based on

Lilly Digest Preliminary Report—1987

Averages per Pharmacy	1986 (Preliminary Sample) (997 Pharmacies)	1985 (Full Sample) (1,378 Pharmacies)	Amount and Percent of Change
	Percent of Sales	Percent of Sales	
Sales			
Prescription	$418,601— 63.3%	$369,595— 62.2%	+$49,006—13.3%
Other	243,009— 36.7%	224,323— 37.8%	+$18,686— 8.3%
Total	$661,610—100.0%	$593,918—100.0%	+$67,692—11.4%
Cost of goods sold	449,278— 67.9%	400,255— 67.4%	+$49,023—12.2%
Gross margin	$212,332— 32.1%	$193,663— 32.6%	+$18,669— 9.6%
Expenses			
Proprietor's salary	$ 38,505— 5.8%	$ 35,196— 5.9%	+$ 3,309— 9.4%
Employees' wages	67,356— 10.2%	60,316— 10.2%	+$ 7,040—11.7%
Rent	15,439— 2.3%	14,166— 2.4%	+$ 1,273— 9.0%
Miscellaneous operating costs	72,823— 11.0%	67,422— 11.3%	+$ 5,401— 8.0%
Total expenses	$194,123— 29.3%	$177,100— 29.8%	+$17,023— 9.6%
Net profit before taxes	$ 18,209— 2.8%	$ 16,563— 2.8%	+$ 1,646— 9.9%
Total income (includes proprietor's salary)	$ 56,714— 8.6%	$ 51,759— 8.7%	+$ 4,955— 9.6%
Inventory at cost			
Prescription	$ 43,415— 10.4%	$ 38,939— 10.5%	+$ 4,476—11.5%
Other	$ 50,648— 20.8%	49,375— 22.0%	+$ 1,273— 2.6%
Total	$ 94,063— 14.2%	$ 88,314— 14.9%	+$ 5,749— 6.5%
Annual rate of turnover of inventory	4.8 times	4.6 times	
Prescriptions dispensed			
New	14,730— 50.1%	14,086— 49.7%	+ 644— 4.6%
Renewed	14,697 — 49.9%	14,261— 50.3%	+ 436— 3.1%
Total	29,427—100.0%	28,347—100.0%	+ 1,080— 3.8%
Average prescription charge	$14.23	$13.04	+$ 1.19— 9.1%
Floor area and	2,886 sq.ft.	2,673 sq.ft.	+ 214— 8.0%
sales per square foot*	$229.25	$219.98	+$ 9.27— 4.2%
Pharmacy hours open	61	62	

* Based on averages of pharmacies that reported all data

patient days shows that inventory during 1986 equaled $2.38 per patient day—up 11 cents—or almost 5% higher than the year earlier. Purchases were $20.82 per patient day, an increase of close to 8%. Because inflation is not taken into account, its influence on inventory and purchases cannot be isolated. Therefore, these figures do not necessarily reflect increased use of pharmaceuticals and related items by hospital patients.

The floor area of the central pharmacy declined about 5% during 1986. This may be explained, in part, by the slight shift in distribution of the overall sample over the two years. It appears that smaller-sized hospitals accounted for a larger share of the total sample during 1986.

The ranking for the top four pharmacy department services was the same for 1986 as for 1985. These services were offered by over 60% of responding hospital pharmacies. However, there was a decline in the percentage of hospitals reporting these staff activities during 1986 when compared with 1985 figures.

Review of a decade of selected operating statistics from past editions of the *Lilly Hospital Pharmacy Survey* reveals the following trends:

- Since 1982, central pharmacy hours open per week increased at a slower rate than during the 1978–1982 period. Had the earlier trend continued, the 1986 average hospital pharmacy would have been open over 100 hours per week.
- The average number of occupied beds declined dramatically since 1981, reversing a significant uptrend. Had the earlier trend continued, one third more beds would have been occupied during 1986.
- Inventory and purchases per occupied bed showed steady, moderate growth of about 8% per year during the past decade.
- Pharmacist and technician hours worked per week per occupied bed increased steadily but moderately since 1978. However, pharmacist hours showed a slightly faster rate of growth than technician hours.

The 1987 issue of the *Survey* will be distributed to hospital pharmacy directors and others interested in hospital pharmacy during August, 1987.

TABLE 1
Average hospital pharmacy

	1986 (2,167 Hospitals)	1985 (1,651 Hospitals)	Percent of Change
Bed capacity	235	244	−3.8%
Class	private nonprofit	private nonprofit	
Profile	General	General	
Census (beds occupied)	59%	60%	
Admissions	8,416	8,566	−1.8%
Patient days	50,607	53,436	
Length of patient stay	6.0 days	6.2 days	
Hours central pharmacy open/week	97	100	−3.1%
Pharmacist hours/week	294 (7.3 FTE)	309 (7.7 FTE)	−5.1%
Technician hours/week	268 (6.7 FTE)	276 (6.9 FTE)	−3.0%
Support personnel hours/week	115 (2.9 FTE)	114 (2.9 FTE)	+0.9%
Inventory	$120,397	$121,198	−0.7%
	$2.38/patient day	$2.27/patient day	+4.8%
	$512/bed	$497/bed	+3.0%
	$868/occupied bed	$828/occupied bed	+4.8%
	$14.31/admission	$14.15/admission	+1.1%
Purchases	$1,053,737	$1,032,831	+2.0%
	$20.82/patient day	$19.33/patient day	+7.7%
	$4,484/bed	$4,233/bed	+5.9%
	$7,600/occupied bed	$7,055/occupied bed	+7.7%
	$125.21/admission	$120.57/admission	+3.8%
Inventory turnover rate	8.7 times	8.5 times	
Floor area (central pharmacy)	1712 sq ft	1799 sq ft	

Services offered by over 60% of pharmacies:

Monitoring patient profiles	94.4%	Monitoring patient profiles	96.5%
Monitoring drug interactions	91.2%	Monitoring drug interactions	92.6%
Providing drug information services	74.6%	Providing drug information services	82.5%
Drug therapy consultation	67.9%	Drug therapy consultation	71.2%

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OUTPATIENT PRESCRIPTION DRUG COVERAGE UNDER MEDICARE

by Peter P. Lamy, Ph.D.

> "Unless community-based alternatives are enhanced, the number and percent of the elderly in need of nursing home care can be expected to increase sharply as the number of elderly over 85 increases. This form of care is expensive, and usually not the preferred care option. . . . there will be an increased need for a variety of community support servies, in-home services, and adult day care. While the older persons of today and tomorrow have greater economic and social resources than in previous decades, there will continue to be disadvantaged subgroups of elderly. If we anticipate and plan for these trends, individuals and families will be much better prepared to cope with these future demands."
>
> *Pennsylvania's Older Population: A Profile*

INTRODUCTION

Anticipating hearings on Medicare reimbursement for outpatient drugs, representatives of the Health Care Financing Administration, the Office of the Minority Counsel of the Senate Select Committee on Aging, and the Office of Technology Assessment (US Congress) requested information from the Center for the Study of Pharmacy and Therapeutics for the Elderly. Questions were raised about generic and therapeutic substitution as cost-containment measures, about acute and chronic problems and their management with drugs, as well as use and cost of drugs.

PRESCRIPTION DRUGS AND THE ELDERLY

The evidence is quite strong that medications used for the elderly is high because of the overall efficacy and cost efficiency of pharmacotherapy compared to alternate medical care technologies. Prescription drugs are still relatively inexpensive compared to more labor or technology intensive modalities of health care. They are and remain the front line of medical care for the elderly and are probably the most cost effective modality of chronic disease management. For example, the use of cimetidiene to control duodenal ulcers resulted in an estimated 26 to 70% saving for Medicaid in Michigan in its first year of use by reducing the need for surgery. Similarly, it has been estimated that lithium treatment of manic-depressive illness has saved $4 billion during the last decade. Enrollment in a pharmaceutical assistance program in New Jersey, following the establishment of that program, was associated with a reduction in expenditures for hospital-based procedures.

This latter point is of extreme importance. Of the 27 million elderly, approximately 25% can probably expect to be stricken with cancer. Antineoplastic agents are covered only when patients are cared for in a hospice or are hospitalized. The daily hospital rate is probably $350/day. A vial of one antineoplastic (chemothera-

TABLE 1
DRUGS MOST FREQUENTLY PRESCRIBED FOR ELDERLY AMBULATORY PATIENTS*

Group 1:
- Cardiovascular
  - Diuretics
  - Heart problems
  - HBP medications
  - Potassium supplements
- Analgesics
- Anti-arthritics

Group 2:
- Anticoagulants
- Psychotropics
- Antibiotics
- Sedatives/hypnotics
- Steroids
- Insulin/oral hypoglycemics

Group 3:
- Anti-seizure medications
- Ulcer medications
- Nutrition supplements
- Thyroid
- Hormones

Data courtesy of D Lago, MA Smyer, F Ahern and M Goodfellow, Pennsylvania State University, Gerontology Center, 1986, The Pennsylvania PACE Program

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Dr. Peter P. Lamy is Professor and Director for The Center for the Study of Pharmacy and Therapeutics for the Elderly, School of Pharmacy and Professor, Epidemiology and Preventive Medicine, School of Medicine, University of Maryland at Baltimore.

I wish to gratefully acknowledge the provision of important data and suggestions from the following faculty members of the School of Pharmacy: Donald O. Fedder, Madeline V. Feinberg, Clarence Fortner, Robert J. Michocki, John O'Connell, Marvin L. Oed, Francis B. Palumbo and the following faculty members of the Pennsylvania State University, Gerontology Center: D Lago, MA Smyer, F Ahern and M Goodfellow.

TABLE 2
THE LEADING CAUSES OF ACTIVITY LIMITATIONS

- Circulatory problems
- Nervousness
- Heart problems
- Digestive problems
- Arthritis/gout
- Urinary tract disorders
- High blood pressure
- Visual problems
- Skin problems
- Hearing problems
- Bronchitis/emphysema
- Osteoporosis

Data courtesy of D Lago, MA Smyer, F Ahern and M Goodfellow, Pennsylvania State University, Gerontology Center, 1986. The Pennsylvania PACE Program

TABLE 3
THE MOST FREQUENTLY USED NON-PRESCRIPTION DRUGS

- Cold medicines
- Antacids
- Cough medicines
- Laxatives
- Anti-diarrheal preparations
- Pain medications
- Skin preparations
- Home remedies
- Vitamins
- Aspirin

Data courtesy of D Lago, MA Smyer, F Ahern and M Goodfellow, Pennsylvania State University, Gerontology Center, 1986. The Pennsylvania PACE Program

peutic) agent may be $90 and the patient may need two to three vials of just this one agent. This does not take into consideration pre-treatment activities, such as hydration, for example. Thus, patients are often hospitalized in an effort to protect them from high drug expenditures. Yet, these drugs could be administered in the home at considerable savings to the system.

The drugs most often used are depicted in Table I. They reflect clearly the 12 leading causes of activity limitations in the elderly (Table II). The non-prescription drugs most often used are listed in Table III. The elderly, about 12% of the population, receive about 32% of all prescription drugs. The majority of older persons use multiple drugs, with 83% of those taking medications using two or more drugs. Fourteen percent use between seven and 15 drugs simultaneously. Some psychiatric patients may receive as many as 22 drugs daily, thus dramatically increasing the well known risk of adverse drug reactions and interactions in the elderly. Several elements contribute to increased drug use among the elderly. Foremost among them is the fact that chronic disabilities afflict about 15% of the general population, but 66% of those 85 years old and over.

A survey of the Pennsylvania population eligible for prescription drug coverage under the PACE program has yield some interesting data. The PACE program represents an innovative approach to cover some of the costs of prescriptions for older adults. There were projected expenditures of over $300 million in benefits to an estimated 590,000 older persons within the first three years.

Approximately 70% of the population surveyed had an annual income of less than $10,000, over 70% were female, 60% and more were widowed, divorced, separated or never married, and one-half visited a physician more than three times a year. About one-third of this population had received four or more prescriptions within two weeks prior to the survey and more than 10% of those did not have a prescription filled. At most 20% of this population had a prescription insurance. It is clear that there is an inverse relationship between income and perception of cost as a problem. In one study, from 1981 when cost of antihypertensive medications were still relatively low, between 22 and 36% of patients reported economic barriers to the purchase of antihypertensive drugs, both new and refill. Between 15 and 36% reported that they were at times unable to purchase their medications. In another survey, the cost of medication was "very much" or "somewhat" a problem for 25% of patients. The cost of some antihypertensive medications is presented in Tables IV–VII.

COST-CONTAINMENT EFFORTS
Current—Not Resolved

There is no question that health care costs are rising. They are rising at a rate of 3% a year and it has been predicted that, if allowed to rise unchecked, they

TABLE 4
APPROXIMATE UNIT COST FOR STEP TWO ANTIHYPERTENSIVES

Drug	Approximate Unit Cost
Reserpine	1.00
Propranolol	8.67
Clonidine	14.00
Methyldopa	14.67
Prazosin	16.67

Adapted from: Luxenberg J, Feigenbaum LZ: The use of reserpine for elderly hypertensive patients. J Am Geriatr Soc 31:556, 1983

TABLE 5
APPROXIMATE ANNUAL COST OF VARIOUS ANTIHYPERTENSIVES

Drug	Approximate Cost ($)
Captopril	442
Methyldopa	204
Propranolol	209

Adapted from: Sahler CP Jr: Antihypertensive therapy and quality-of-life. (Letter) N Engl J Med 316:52, 1987 could consume 20% of the Gross National Product (GNP) by the year 2004. However, mandated cost containment measures, as is seen with generic (multisource drugs) and therapeutic (single-source drugs) substitution applied indiscriminately and directed according to vague guidances may mean that for the first time in the history of the United States problems of an individual must be traded for the economic good of society.

Generic Substitution: It is delusional to automatically equate generic substitution with the achievement of cost containment. On average, generic drugs do cost less than do branded drugs, but for some drugs the difference in mean price is trivially small and, in some instances, the cost of the generic drug is greater than that for a branded drug. Moreover, and more importantly, despite FDA assurances, uncertainties still remain, and, while major studies are lacking (who would fund them?), sufficient anecdotal evidence continues to mount and increase the uncertainties. Mandated, indiscriminate "switching" from one drug product to another (be it from a branded to a generic or generic to generic) does not take into account "critical" drugs, "critical" diseases and "critical" patients. Clearly, there is evidence that generic products are not always uniformly equivalent to branded drugs.

Therapeutic Substitution: This represents an effort to overcome costs of single-source drugs. It occurs in about 50% of hospitals and managed care systems, where, theoretically, a committee judges the appropriateness of substitution. Plans are under way to expand these efforts to the community, where the scientific/clinical input will be lacking and where governmental agencies, ased on cost considerations alone, may mandate substitution. The potential for clinical inequivalence due to different chemical configuration of the drug molecules, due to change in dosage forms etc. is much greater following therapeutic substitution compared with generic substitution. Indeed, therapeutic substitution may alter therapeutic outcome, subject patients to substantial and unnecessary risk and increase cost instead of reducing it.

LACK OF COST-CONTAINMENT EFFORTS

Making medications available for management of chronic diseases and for acute catastrophic events will only be a tentative approach to a more cost-effective use of drugs. One should consider other factors to make drug therapy optimal.

TABLE 6
APPROXIMATE UNIT COST FOR VARIOUS ANTIHYPERTENSIVES*

Drug	Approximate Unit Cost
Diuretic	1.0
Diuretic plus pot.-sparing drug	1.1
Diuretic plus pot. supplement	2.67
Beta blocker	2.23
ACE inhibitor	4.67
Calcium channel blocker	8.33

*Drug Cost + 10% + Dispensing Fee
Adapted from: Pauly MV: The changing health care environment. Am J Med 81 (Suppl C):3, 1986

TABLE 7
APPROXIMATE UNIT COSTS AT DIFFERENT DISPENSING SITES IN THE U.K.

Drug	Hospital	Retail
Bendrofluazide, 5 mg daily	1	2.67
Propranolol, 80 mg BID	4	9.34–46.7
Atenolol, 100 mg daily	60	121.3

Adapted from: Sever PS: 1985—the year of the hypertensive trials: interpreting the results. TIPS 7:134, 1986

Redefinition of the "Ambulatory" Patient: "Ambulatory" has been defined as a patient not institutionalized. Implied in that definition has been the acceptance that the patient could present at a clinic for treatment. Care settings have changed. Home care is the fastest-growing segment of the health care market. For every patient residing in a nursing home, there are already four living in the community of comparable age and afflicted with equally serious medical problems. Thus, the patient may well be bed-bound or home-bound and could not be classified under the old classification of "ambulatory". "Not institutionalized" would be a much more descriptive and accurate classification.

Monitoring and Intervention—Non-Pharmacologic Approach: Therapy for chronic illness involves both pharmacologic and non-pharmacologic modalities. Approaching the broad scope of both of these requires the utilization of professional skills that include patient education, monitoring, counseling and follow-up. For hypertension, for example, this would involve dietary changes, cessation of smoking and alcohol intake, exercise, and still other approaches. Yet, in health care planning, and particularly in planning reimbursement, little or no consideration is given to the provision of these services, and, especially, for providing payment for these services.

Monitoring and Intervention—Compliance: In 1984, there were more than 125,000 deaths and several hundred thousand hospitalizations due to noncompliance with cardiovascular drugs alone (six of the 10 most frequently used drugs for patients 75 years old and over are cardiovascular drugs). In addition, approximately 20 million work days were lost representing an overall cost of $1.5 billion to the national economy simply because prescribed cardiovascular drugs were not taken properly. HHS Assistant Secretary Robert Windom and FDA Commissioner Frank Young have correctly termed this "the other drug problem". They have stated that up to one-half of the 1.6 billion prescriptions each year are taken improperly. Pharmacists' (and other health care specialists') intervention and compliance efforts have proven that this problem can be alleviated to a large degree. Efforts, though, are limited due to lack of reimbursement policies.

Compliance Packing: The United States Pharmacopoeia has approved "Med-Pak". Studies have shown that over 20% of all admission of elderly to institutions are due to the patient's inability to handle medications. Medicaid has consistantly refused to reimburse for packaging which will, among other benefits, enhance the patient's ability to remain at home by making it easier to self-administer medications.

Monitoring and Intervention—Therapeutic Outcome: The OTA has stated that drugs are the most cost-effective modality of long term care diseases management, but that little is known about drug action when multiple drugs are used. The Royal College of Physicians has stated that one of the three major reasons for adverse drug reactions in the elderly is poor supervision of chronic care medications. Ten to 15% of admissions of elderly to hospitals are due to adverse drug reactions and, in the latest ADR report, the FDA has shown that people over 60 (17% of the population) accounted for one-third of all hospitalizations due to ADRs and nearly 50% of all death reports. On the other hand, in a large scale study, it was shown that nearly 68% of all drug interactions and ADRs could have been avoided and another 18% could probably have been avoided had current knowledge been applied. Pharmacists fulfill a medication review function in skilled nursing facilities (mandated by the Federal Government) but have not been assigned the monitoring function in the long-term care home sector. They should be.

CURRENT MEDICARE REIMBURSEMENT FOR OUTPATIENTS

Note: The following information applies to persons eligible under Medicare Part B. Medicaid patients, of course, are reimbursed. Patients with Supplemental Insurance may recover some drugs costs.

Current Medicare Drug Coverage: Drugs, per se, are *not* covered. However, there is a "back-door" approach. Under prosthetic device coverage, parenteral and enteral nutrition are reimbursed. A major problem exists. Use is approved only for patients unable to swallow and patients with malabsorption problems. Furthermore, treatment must be indefinite. Indefinite means that treatment must be given for more than 90 days. Patients who could benefit from a 60 day treatment are not eligible (cost could be $15,000). A major problem exists with the timeliness of reimbursement. Some pharmacists literally have over $100,000 outstanding, awaiting reimbursement.

Under durable medical equipment coverage, low volume infusion pumps are reimbursed and drugs used with these pumps are, therefore, also reimbursed. That would cover pain medication (morphine infusion), chelation therapy (iron overload) and insulin. Also covered would be chemotherapeutic agents (for colorectal cancer, for example), but *not* antibiotics.

Lack of Coverage: Antibiotics are not covered. Patients with life-threatening diseases such as osteomyelitis, endocarditis, and diverticulitis, in order to receive the necessary antibiotic infusion therapy, must be hospitalized. While antibiotics used in these instances may not be too expensive, there are cases where a patient may be penicillin-sensitive and more expensive drugs, such as vancomycin, must be used. A problem of the near future is AIDS. Elderly patients may have contacted AIDS via blood transfusions, and antibiotic treatment will be necessary.

APPENDIX A

ONE COUPLE'S DRUG EXPENSES

B and J live in a Baltimore suburb. His mother receives blood transfusions weekly (leukemia). She is 93. Her mother (92) is in a nursing home with Alzheimer's. Both are in their 60s. Both have glaucoma, he also has hypertension.

B:	J:
Timoptic	Timoptic
Pilocarpine	Pilocarpine
Propine	Propine
Tenoretic	
Annual Total: $670	$270

The importance of antibiotics in the management of the elderly chronic care patient can be underscored with data from one mixed skilled/intermediate 97 bed facility. There was no influenza and no patient suffered from bed sores. Of the 97 patients, 22 were receiving antibiotics for a wide range of problems. Drug cost (without dispensing or monitoring or laboratory fees) was over $500 for the month reported.

RE-IMBURSEMENT FOR PRESCRIPTION DRUGS

Cost of Some Medications: Anti-ulcer drugs may cost $50 to $60/100, antibiotics $90 to $100/100, and anti-inflammatory drugs $100 to $120/100. Drugs on the horizon, such as Tissue Plasminogen Activators, to be given within 6 hrs after a myocardial infarction, may cost as much as $1,000/treatment. Reimbursement of drugs alone may not be sufficient. A diabetic patient, for example, will need syringes and needles, urine testing equipment, and other items to be used in conjunction with medication to optimize medication effect. Lack of that would negate, in many instances, the effectiveness of management of the disease.

Reimbursement: It would be difficult, if not unfair, to single out any major drug category. It may well be possible to approve (prior approval) for reimbursement "standard" drugs, such as hydrochlorthiazide for the management of hypertension, for example. There may also be an upper limit. However, on documentation by the prescribing physician that a particular patient is unable to tolerate side effects of the "standard drug" and that a newer, likely more costly, agent would be necessary, the other agent could be reimbursed. There should also be a time limit, which will force re-evaluation of the need for any chronic care drug.

Given that there is likely to be a great deal of resistance to coverage of outpatient drugs under Medicare, one method which might prove politically palatable would be an indemnification program. Under this scheme, the patient would be responsible to the pharmacy for his own drug bills and would then submit claims for reimbursement directly to Medicare. This would accomplish several objectives:

1. As mentioned before, it may be an acceptable first step.
2. It would also offer a great deal of flexibility. Drugs could be added a few at a time and could initially be placed on a "formulary" by class of diagnosis category.
3. Cost controls could be implemented such as deductible and/or coinsurance or copayment. The distinction:
   a. Deductible (independent of other Medicare deductibles): The patient pays a first dollar amount per year for his drugs, say $50.00. This drastically reduces program administrative costs and transfers at least the first $50.00 from the program to the patient. (I believe HCFA will propose a $500.00 dollar amount, which seems unreasonably high.)
   b. Coinsurance: The program pays a certain percentage (e.g. 80%) and the patient pays the remainder for all drugs.
   c. Copayment: The patient pays a fixed dollar amount out of pocket per prescription and is not reimbursed for this copayment.

   Copayments, deductibles and coinsurance can be mixed together in a total program.

AN ADDITIONAL PROPOSAL: SELECTED COVERAGE OF NON PRESCRIPTION DRUGS

Non-prescription drugs are widely used in long-term care. In nursing homes, 40% of all drugs used are non-prescription drugs. Non-prescription drug use no longer depends on self-diagnosis. Indeed, the diagnosis of "pancreatic enzyme deficiency" must be made by a physician, who can then "prescribe" a non-prescription drug. Certainly, pain medications (acetaminophen, aspirin) have been found to be effective in mild to moderate cancer pain. Aspirin is, in patients not aspirin-sensitive, effective in the management of rheumatoid arthritis and osteroarthritis. Antacids, used in the treatment of active ulcers and prevention of recurring ulcers, are effective. Thus, in order to avoid costly prescription drug use, in cases where this may be possible, non-prescription drugs could well be used, more cost-effectively, if reimbursed.

Editors Note: At Press time, the House of Representatives had passed HR 2470 and action was expected in the Senate on a bill to cover outpatient prescription drugs under Medicare. Stay tuned.

Drug Policy Center Established at Pharmacy School

A new multidisciplinary research unit established by the University of Maryland will focus on the use of prescription and over-the-counter drugs. The Center on Drugs and Public Policy will examine policy issues related to the development, prescribing, administration and use of medications, as well as quality, cost, and reimbursement concerns.

In addition to research, the Center will sponsor symposia and workshops on current drug policy issues. Fellowships for university, industry and government scholars seeking to initiate drug-related policy studies will be available.

Center Director David A. Knapp notes, "The goal of the new unit is to provide an objective source of data and analysis to those engaged in public policy debates on drug issues. We don't plan to take sides in these debates but rather to help assure that matters of quality, access and cost are fully and rationally explored before decisions are made."

The Center on Drugs and Public Policy is a joint venture by the School of Pharmacy and the Policy Sciences Graduate Program on the Baltimore campuses of the University of Maryland. The Center combines expertise in drug and pharmacy issues with that of economists and political scientists.

In announcing the Center, Maryland Governor William Donald Schaefer commented that the Center was established "to make sure that some of the problems related to good drugs don't get ignored in the face of our very real concern with the problem of bad drugs." He continued, "The Center is a unique, multidisciplinary approach to the issue, combining the talents of faculty in the health sciences with economists, political scientists, and public policy specialists."

Center Director Knapp is professor of pharmacy practice and administrative science at the School of Pharmacy. Associate directors of the Center include Dr. David Colby, currently a Robert Wood Johnson faculty fellow in health care finance, and Dr. Francis Palumbo, a pharmacist-attorney and associate professor at the School of Pharmacy. Dr. George LaNoue, professor and chairman of the Policy Science Graduate Program, chairs the University Board of Advisors to the Center.

Morgenroth Award Presented by ACA

Paul M. Armstrong, immediate Past-President of the American College of Apothecaries, was presented the Victor H. Morgenroth, Jr. Memorial Award at the College's 47th Annual Conference conducted in San Diego, California. The award consists of a beautifully framed print of Andrew Craigie, America's first Apothecary General, plus a $1,000 contribution in the Past-President's name to the Research and Education Foundation of the ACA. This contribution will establish Armstrong as a Life Member in the Foundation.

Paul M. Armstrong was born and raised near Salt Lake City, Utah and graduated from the University of Utah College of Pharmacy in 1952. He currently owns and operates three professional pharmacies in Flagstaff and Williams, Arizona.

LETTERS

Dear Dave:

What are the issues facing our profession?

- Continuing education
- DRG's
- DUR
- Third parties
- Physician dispensing
- Keeping up with therapeutics
- Etc, etc.

These issues have prompted a group of pharmacists from the Washington Metropolitan Area to re-activate the Prince Georges/Montgomery County affiliate of the Maryland Pharmacist Association. The primary goal of this "reformulated" association is to provide quality continuing education in a convenient location. We are presently finalizing plans for a fall program with additional programs for early and late spring.

Please watch for further announcements. In the meantime, please refer any questions, comments, or suggestions to:

Gary Magnus, M.S.	774-1719
or	
Beverly Yachmetz, P.D.	253-5845

October is "Talk About Prescriptions" Month sponsored by MPhA and NCPIE. Reproduce this flyer and the one on page 7 to distribute to your patients.

MEDICATION MEMO

Check (✓) the small box next to the questions you want to ask your doctor, pharmacist, or other health professional. Keep this Medication Memo as a reminder and write down the answers.

☐ What is the name of the drug and what is it supposed to do?

Name of medicine

Purpose of this medicine

☐ How and when do I take it—and for how long?

Other instructions

☐ What foods, drinks, other medicines, or activities should I avoid while taking this drug?

Foods to avoid

Drinks to avoid

Medicines to avoid

Activities to avoid

☐ Are there any side effects and what do I do if they occur?

Possible side effects

What to do if they occur?

☐ Is there any written information available about the drug?

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by Jim Dickinson

Could you fake a small IQ to land a job like that—$39,000 a year to start plus $10,000 in productivity bonuses? Hundreds of pharmacists—especially new college graduates anxious to pay off a heavy loan burden—are answering the seductive call of the hottest new practice setting in the profession.

But all that glitters is not gold, as seven Medco/National pharmacists told me in a taped, three-hour confidential disclosure session recently. They got sick of shipping intermingled drugs when dispensing speed overtook dispensing quality.

But until then, their working conditions were simply idyllic. "We worked 9–5, had every weekend off and we didn't have to sell baby diapers. We had plenty of patient and physician dialog (admittedly only by telephone), and we had access to patient profiles. National even bought us subs at lunch time. It was a dream come true. No pharmacist could want more."

Then everything changed. Coinciding with an avalanche of new employee benefit prescription contracts, National had to contend with a damaging, widely-publicized PCS survey on mail-order prescription costs that found them not to be cost-effective due to wastage rates.

Not only did National have much more business to service, but now it had to defend it in ever-deeper discounting. The company's response was to crank up the prescription line, from a leisurely (!) 50 Rxs/hour to 70-plus, and to extend the checking pharmacists' hours on-line from four to eight. The line's error rate soared.

The pharmacist-checking process is supposed to assure that the dosage units in the outgoing vials are true to label and true to prescription, but the line's speed, boosted by greed in the volume-based bonus system (15 cents bonus for every Rx by which the pharmacists' checking average exceeds 50/hour) makes for blurry checking.

Only the top layer of tablets, capsules, pills in a vial can be eye-balled.

One informant-pharmacist, who was making five figures in productivity bonuses on top of salary before rebelling, put it this way: "I was checking 75 Rxs an hour; it got so I couldn't remember what I had just checked."

And the pharmacists were never far from their non-pharmacist supervisors' taunts: "If a tech can do 60 an hour, why can't a pharmacist do it quicker?"

Another of my informants provided me with a 77-item list of errors personally observed during a thirty-day period. The pharmacists estimated that they rejected 5% of all prescriptions processed.

Worse, the rejects were all dumped, together, in large "Return To Stock" cartons at the end of each day, for redistribution by technicians to their originating Baker dispensing units and rotating trays in the filling area.

That's probably where the intermingling begins. One white tablet of Proventil 2 mg looks exactly like one white tablet of Lanoxin 0.25 mg, to a technician. Only a pharmacist can tell them apart, and even then it takes more than a trained eye—it takes a little time, which is something that National does not have to spare.

My informants testified—on tape—that many interminglings routinely occur, and any resulting complaints are dealt with in a top-security Customer Relations Department that pharmacists are discouraged from entering, and where patient records are kept away from effective access to line pharmacists.

One complaint in April that did escape the seal and become known on the floor was a phoned-in emergency involving a female Lanoxin patient with arrythmias from taking intermingled Proventil.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

National's response to errors, my informants said, was to send a headquarters executive to give assembled pharmacists a "pep" talk and to warn them that the consequences of making mistakes would be "elimination." Plant procedures remained unchanged, however.

The pressure continued to build, and the pharmacists began to forget that they were making the best money in the profession. They began grumbling, and morale fell to a serious low.

That's when a new management bulletin was issued. A two-column specifications sheet, one side bore the heading "What we *are* looking for or at," and the other, "What we *are not* looking for or at."

According to this, the first desirable trait was "big picture oriented" (despite the fact that National ensures that its pharmacists know only what is involved in their immediate task, and vigorously discourages pharmacists going into other areas); the first undesirable trait in a pharmacist, according to the list, was high IQ.

Other sought-after attributes in the first column were: "High ethical/professional standards, aggressive, high energy level, not petty, can make tough decisions, objective, ability to communicate with management. . . ." And on the other side, detriments included "on-line checking average, charisma, ability to socialize, ability to amuse, people who own a wristwatch (clockwatchers), people who are concerned with what they're going to make this week, people who are focused upon the almighty dollar, clowns and circus acts. . . ."

Clearly, National was determined to quell dissent and to impose its standards on the pharmacists. So, my informants said, they took their complaints to the Pharmacy Board, and were astonished at the reaction they got.

"He (the board exec) told me they couldn't do an inspection without solid documentation and evidence, and even then they were required to give the plant notice before the inspection, because of 'security'," the pharmacist who made the anonymous call to the board said.

The National plant was not inspected as a result of this complaint.

Perhaps, because mail-order pharmacy operations compete mainly with out-of-state pharmacies, they are viewed as a trouble-free, net asset to the state, bringing needed dollars in and boosting employment. This especially benefits minimum-wage ethnic groups who have little command of the English language and who are most likely to be intimidated by their supervisors.

What's National's side of the story? Five phone calls and a certified letter to president Martin Wygod yielded no response.

As you read this, one National facility (in Ohio) and the state's pharmacy board are being sued by the state pharmacy association over the board's failure to police a state law that prohibits dispensing of out-of-state prescriptions. Trial date is September 8.

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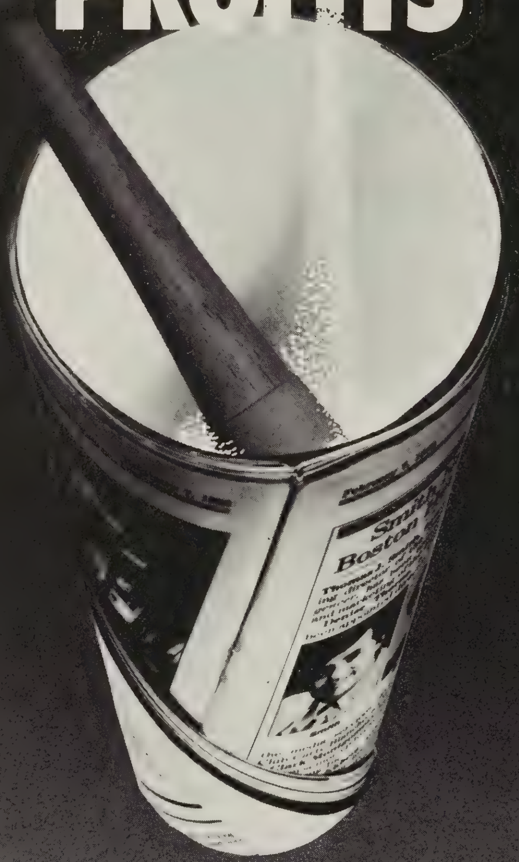

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Members of the Chemists' Guild of New Zealand recently visited the MPhA to discuss market influences on retail pharmacy practice in America. Shown following this discussions are: (left to right) Wayne Van Wie, U. of M. Pharmacy Student; Mark Erwin, C.G.N.Z. Marketing Director; John Olson C.G.N.Z. Executive Director; and Brian Sanderoff, MPhA Speaker of the House.

The School of Pharmacy hosted a breakfast reception in honor of William Heller, Executive Director of the United States Pharmacopeial Convention (left) who received an honorary doctoral degree from the University of Maryland. School of Pharmacy Dean William J. Kinnard, Jr. (right) reviews the ceremony with Dr. Heller.

Robert Beardsley, associate profession of pharmacy practice and administrative science at the School of Pharmacy was voted Teacher of the Year by the 1987 graduating class.

Ronald L. Kaye, M.D. (left) and Roberta Brown, Pharm.D. (right) were the faculty for the Continuing Education Coordinating Council's C.E. program on "Arthritis Assessment" held near the Baltimore inner harbor and sponsored by Syntex Labs.

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

If individuals would like to receive a free copy of our Melanoma pamphlet, have them send a self-addressed, stamped envelope to:

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When it comes to medicines, what you don't know *can* hurt you.
A message from the United States Pharmacopeia, WBAL TV and Maryland Pharmacists Association.

calendar

Oct 9–11—MSHP ANNUAL SEMINAR—WILLIAMSBURG, VA
Oct 18–23—NARD Convention
Oct 23–26—MPhA Trip to Nassau, Bahamas
Oct 23–25—Post NARD Convention side trip to San Francisco
Oct 25–Nov 1—APhA Midyear Meeting, Baltimore, MD
Jan 17–24 (88)—MPhA Trip to Curacao in the Caribbean

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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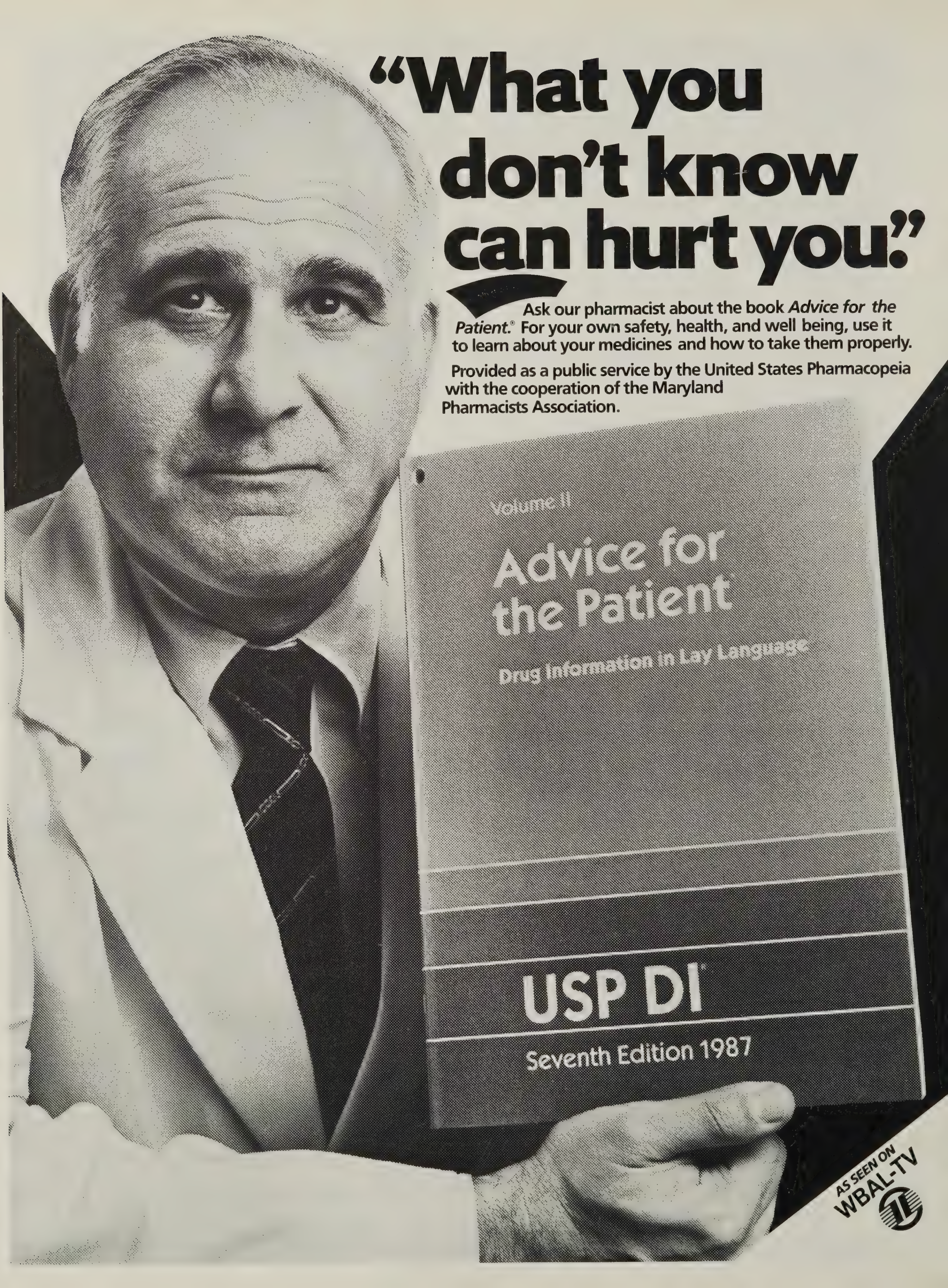
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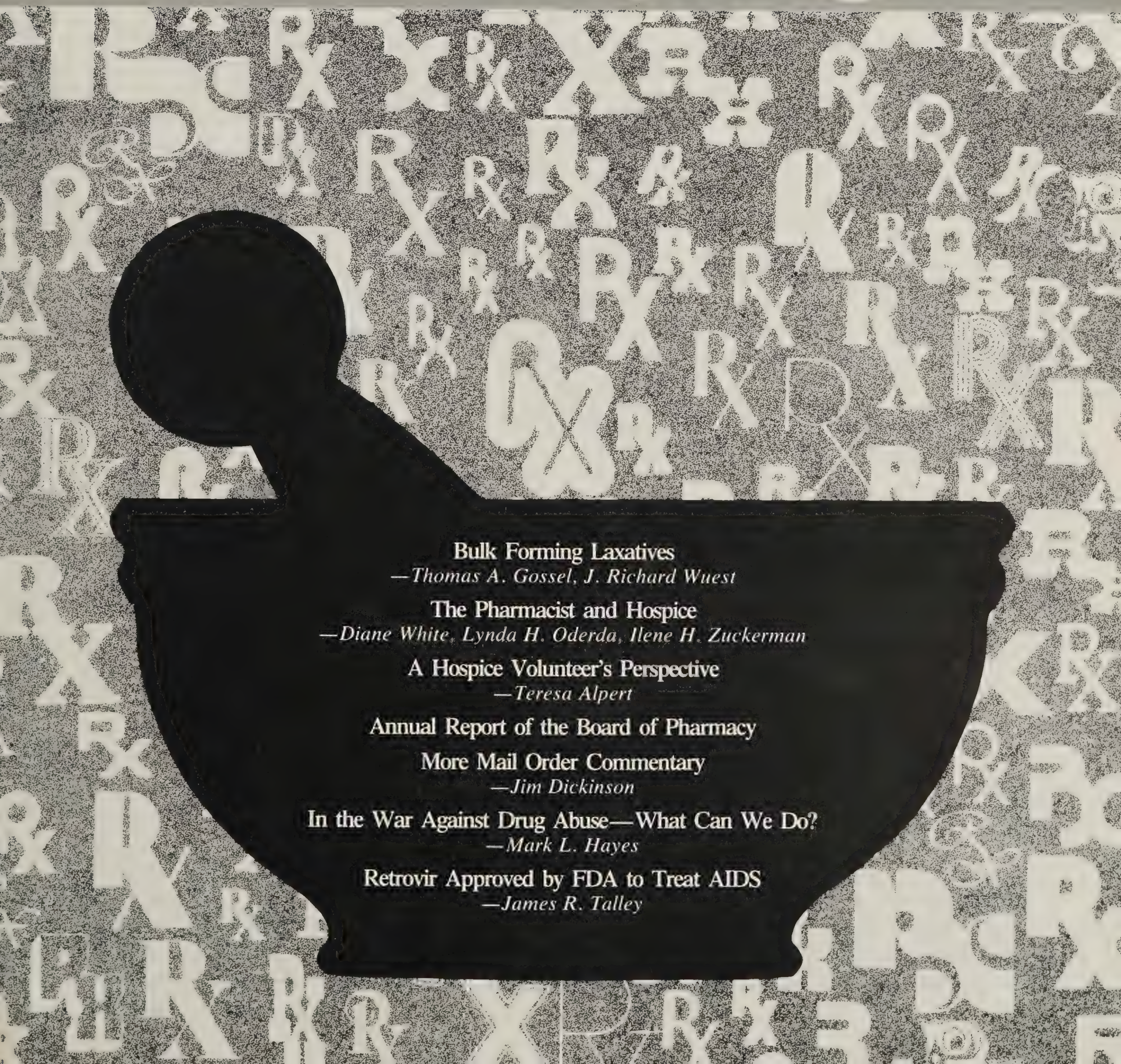

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The Pharmacist and Hospice
—Diane White, Lynda H. Oderda, Ilene H. Zuckerman

A Hospice Volunteer's Perspective
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I read with great interest a recent journal article that linked a few mail order operations and repackers for dispensing physicians, with companies that deal heavily in diverted prescription drugs. Apparently there is less government scrutiny of these retail operations than there would be of sales transactions at the wholesale level. This enables these companies to market large quantities of illicit drugs without detection.

While this revelation is shocking it is just one more example of the secondary drug distribution network that has developed due to the tremendous disparity between what some manufacturers charge for profit, tax paying accounts, such as retail pharmacists and the prices they charge other accounts, such as some non-profit HMO's and Hospitals. This network, which lacks the regulation of the traditional systems, is also susceptible to penetration by unscrupulous individuals who have introduced counterfeit medications into the drug distribution system. Congress, realizing the severity of this problem, is contemplating legislation to attempt to eliminate this activity, but as long as there is an opportunity to reap windfall profits this practice will continue.

Now is the time for all manufacturers to establish one fair price for their products and charge all their accounts accordingly. This would curtail almost overnight this secondary distribution network and restore the confidence that both pharmacists and the consuming public have in the quality and composition of prescription medications.

Lee Ahlstrom, P.D.

PRESIDENT

CONTINUING EDUCATION FOR PHARMACISTS

VOL. IV, NO. 9

Bulk Forming Laxatives

by **Thomas A. Gossel, R.Ph., Ph.D.**
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. discuss the bulk forming laxatives, describing their actions, uses, and special requirements for safe use; and
2. explain important differences in the various bulk forming laxatives.

Objectives

At the conclusion of this lesson, participants will be able to:

1. list the various bulk forming laxatives and explain their mechanism of action;
2. explain how the various drugs differ from one another;
3. exhibit an understanding of the warnings and precautions associated with their use; and
4. state important points of information about these products that consumers must understand in order to take them correctly.

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Americans spend approximately $500,000,000 annually on laxatives, and the market is increasing by about 10 percent per year. Sixty-four percent of this amount is spent in pharmacies. Therefore, pharmacists are actively involved in providing a wide selection of items, as well as in transmitting important information to consumers contemplating using them.

Bulk forming laxatives and stimulant laxatives currently share the largest segment of this market, with the bulk formers leading the two. Geriatrics use most of the laxative products and the U.S. population of individuals over age 65 is increasing.

This lesson explores the topic of bulk forming laxatives. It discusses their actions and adverse reactions, uses and precautions, and major differences. It also presents important advice for consumers.

Constipation and Laxative Use

Preoccupation with the bowels and self-purgation as a daily ritual are engrained in the thinking of many Americans. Advertising encourages American consumers to feel guilty if they do not experience at least one bowel movement each day. Accordingly, a sizeable segment of the population also has misconceptions about bowel movements.

The normal number of bowel movements in a specified time varies greatly. One study of 1,455 subjects concluded that 98 percent experienced from 3 bowel movements a day to 3 a week. As few as one bowel movement a week may be normal for some individuals.

Most persons who use laxatives take them for "constipation." Constipation in its scientific sense refers to infrequency or difficulty in passing stools. However, in America, constipation largely refers to a dissatisfaction with the frequency of bowel movements.

Constipation is classified as hypertonic (spastic) or hypotonic (atonic). **Hypertonic constipation** is frequently a part of the irritable bowel syndrome, and is often associated with lower abdominal cramping and frequent alteration in bowel habits, fluctuating from constipation to diarrhea. The condition may begin at any point in life, but the most common is late in adolescence or early adult life. In this condition, the stool is distinctively pellet-like (scybalous) or excreted in thin ribbons, and may even change shape from day to day. The presence of a pellet-like stool is evidence of segmental contraction of the sigmoid colon which identifies one of the major pathophysiologic characteristics of the irritable bowel syndrome.

Hypotonic constipation is most commonly encountered by geriatrics, although it is sometimes seen in younger people. It is more prevalent in women. There is a tendency toward fecal impaction from infrequency. There may also be discomfort in the lower bowel, and the individual may feel bloated or have abdominal discomfort from distension or a feeling of fullness. Hypotonic constipation usually results from faulty bowel habits such as ignoring the urge to defecate, or from a low-residue diet.

Bowel Movements. These are basically a function of the quantity of undigested, unabsorbed residue remaining after the body has removed whatever it can for its nutritional needs. Bowel movements are brought on by the nature of food eaten, time of day, proximity to and familiarity with a particular toilet, psychological factors, amount of exercise and other environmental influences. The two most important factors, however, are the amount of residue and water left from what has been ingested. The greater the amount of undigested residue and water, the more frequent the number of bowel movements.

While fecal material is predominantly water (70 percent), unabsorbed residue accounts for 20 percent of the weight. The remainder consists of dead bacteria, intestinal secretions and other substances. There is no doubt that the amount of bulk in the fecal mass serves an important function in maintaining the proper functioning of the colon.

When the colon fills, nerve impulses signal the brain that the substance should be expelled (defecation reflex). If the afferent stimulus from the rectum does not reach the brain, or is inadequate, or if there is no efferent response generated when it does reach the brain, defecation will not occur. Assuming that the nervous impulses are working well, and the urge to defecate is initiated but the act is not carried to completion, muscular contraction can eventually lessen or be lost. This suppression of voluntary stool passage is believed to be a major cause of constipation. In time, the patient becomes less aware of rectal fullness. Eventually, bowel movements become progressively less frequent and more difficult. The individual may develop hemorrhoids or anal fissures from straining and passing hard stools, which make defecation even more difficult. The ultimate outcome is that the individual begins to rely on chronic use of laxatives or enemas, without which defecation becomes almost impossible. Thus, a "self-imposed" constipation results. A similar phenomenon can occur with the prolonged use of stimulant laxatives. Because of continuous exogenous irritation of the bowel, the physiological impulse described above atrophies.

A lessening of force of the defecation reflex occurs in older persons, especially those who are relatively inactive or confined to bed. This natural loss of tonicity of the rectal muscles occurs as a result of aging or inactivity. The rectum gradually becomes more dilated than earlier in life, and is capable of holding a larger quantity of residue. There is, therefore, a reduction in the frequency of bowel movements. This is not pathologic, and geriatrics are better off avoiding the stronger laxative syndrome.

Bulk Forming Laxatives

The amount of dietary fiber an individual ingests and his chance of becoming constipated are inversely related. Most dietary fiber is carbohydrate (polysaccharide). Some originates from within the cells of plants (such as gums, mucilages, hemicellulose). Others, which are generally referred to as crude fiber, are constituents of plant cell walls. This latter group is subdivided into the carbohydrate and non-carbohydrate portion which is called lignin. Lignin is a substance related to cellulose. Together, lignin and cellulose form the woody cell walls of plants and the cementing materials between them.

Since the most important factor in determining the frequency and volume of bowel movements is the amount of unabsorbed residue from food intake and its water content, increasing dietary fiber will increase both frequency and volume of stools. Those who obtain psychological support from a well-formed, bulky, daily bowel movement should increase ingestion of fiber-rich foods. An alternative method is to use bulk forming laxatives.

Bulk forming laxatives (Table 1) are also called high fiber laxatives. They are defined as natural or semisynthetic polysaccharides and cellulose derivatives which promote evacuation of the bowel by increasing the bulk volume and water content of the stool. This helps soften the stool, promote peristalsis, and stimulate the defecation reflex, to enable the stool to be passed more easily.

Bulk forming laxatives are preferred over stimulant laxatives and drugs of other pharmacological classes for several reasons. They more closely approximate the physiological mechanisms for promoting defecation. They have a low incidence of side effects. They are not habit forming. They do not create a sense of urgency before elimination. Because of a growing realization by Americans that a high fiber diet is healthful, the bulk forming products have become even more popular.

TABLE 1

Safe and Effective Ingredients of OTC Bulk Forming Laxatives
Bran
Calcium polycarbophil
Karaya
Malt soup extract
Methylcellulose
Polycarbophil
Psyllium/Plantago
Sodium carboxymethylcellulose

Not all bulk forming laxatives are equally acceptable to all patients, and not all of them are equally effective. Some have a disagreeable taste. Some, especially the psyllium derivatives, have a gritty texture and unacceptable "mouth feel." Some contain relatively large amounts of sodium and/or potassium, and are contraindicated in persons with cardiovascular and/or renal disease. Because of added flavorings and sweetening agents, some contain significant calories.

Bran is usually taken in the diet in foods such as cereals and whole wheat breads. Bran contains more than 40 percent dietary fiber. It is normally obtained from milling of wheat, but it may be obtained from a number of sources. Wheat bran is largely hemicellulose, cellulose, and "crude fiber" of unknown composition.

The laxative action of bran is probably related to its hydrophilic properties, as well as to a direct action on the colon by some as yet unidentified substances produced by bacterial action on bran.

Bran is safe and effective in doses of approximately 6 to 14 gm/day. There is no specific dosage limitation.

Cellulose Derivatives, Semi-Synthetic. Methylcellulose and sodium carboxymethylcellulose are safe and effective laxatives in doses up to 4 to 6 gm/day. Methylcellulose has been used as a stabilizer and thickening agent in food products since the mid-1940s. It has been used pharmaceutically in ophthalmic and nasal preparations, burn medications, in liquid dentifrices, toothpastes, hair fixatives, creams and lotions.

When mixed with water, these hydrophilic substances produce a clear to opalescent, viscous colloidal solution with a pH of approximately 7.0. The solution loses fluid in the intestine to form a gel, which increases the bulk of the stool. Methylcellulose reportedly acts as effectively as psyllium without the disagreeable taste or texture.

Methylcellulose differs from products obtained from natural sources in the manner in which it takes up water. Psyllium and other plant-derived products absorb water like a sponge. Methylcellulose forms a colloidal solution in any concentration, ranging from a thin solution to a thicker gel. This property makes it potentially safer in that it is less likely to produce impaction.

Karaya (sterculia gum). Karaya is a vegetable gum obtained from the barks of various species of sterculia and cochlospermium. These substances are polysaccharides that absorb water and increase the bulk of the stool. Karaya is safe and effective when taken in doses of 5 to 10 gm/day.

Malt Soup Extract. Malt soup extract is obtained from the partially germinated grain of one or more varieties of barley containing amylolytic enzymes. The evaporated aqueous portion is the malt soup extract, and contains 73 percent maltose, 7 percent protein, and 1.5 percent potassium. Malt soup extract is safe and effective in doses of 12 to 64 gm/day.

Malt soup extract, like the other bulk forming laxatives, works by increasing fecal volume. It also softens the stool by another, as yet unidentified, action. It lowers the fecal pH probably as a result of bacterial conversion of maltose to lactic and pyruvic acids, and carbon dioxide. The laxative apparently exerts part of its beneficial effect as a result of this lowered pH.

Studies have shown that lowering the pH in the cecum and proximal section of the large intestine sets off the propulsive waves of peristalsis that account for the expulsion of stools. In fact, that is the mechanism of action of lactulose (Chronulac), the laxative available on prescription only.

Polycarbophil. This is a hydrophilic polyacrylic resin (polyacrylic acid crosslinked with divinyl glycol). It has a marked ability to bind with water and, therefore, absorbs about 60 times its original weight. This hydrophilic attraction for fluid is reportedly greater with polycarbophil than for any other bulk forming laxative. As a result, this property is the basis for its dual role, that of treating both constipation and diarrhea. Polycarbophil is safe and effective in doses of 4 to 6 gm/day.

In diarrhea, it is presumed that polycarbophil absorbs free fecal water to form a gel in the intestinal lumen. This reduces the urge to eliminate the intestinal contents. With constipation, its retention of water opposes dehydrating, and, therefore, constipating forces in the bowel.

Psyllium Preparations. These include plantago seed, plantago ovata husks, psyllium (hemicellulose), psyllium hydrophilic muciloid (psyllium hydrocolloid), psyllium seed, blond psyllium seed, and psyllium seed husks. Psyllium preparations are obtained from the seeds of various species of *Plantago psyllium*, *P. ovata*, and *P. indica*. The dry, ripe seeds contain a large amount of mucilage. This mucilage acts by imbibing water and increasing the fecal bulk. Psyllium preparations are safe and effective in doses of 2.5 to 30 gm/day.

Psyllium has traditionally constituted the major component of most bulk laxative products. But, as stated before, its taste and texture are considered unpleasant by many consumers. It doesn't fully dissolve in water, leaving a gritty slurry to be ingested. It is also degraded in the digestive process, so it can cause gas and cramping.

Side Effects of Bulk Forming Laxatives. The FDA Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic and Antiemetic Drug Products reported that bulk forming laxatives were among the safest of all laxatives, when used as directed. Adverse effects are rare. Those most often reported include flatulence and defecation of excessively soft stools.

Obstructions of the esophagus, stomach, small and large intestines have occurred. Persons with difficulty in swallowing should not use the products because of the danger of esophageal obstruction. Persons with intestinal stenosis, ulcerations or disabling adhesions should not use them due to possible fecal impaction or intestinal obstruction.

Occasionally, an allergic sensitivity to plant derivatives is noted. There have also been reports of serious bronchospasm following inhalation of the dry powder. Bulk forming laxatives may be contraindicated in persons such as those with significant renal disease who must restrict their fluid intake.

Cellulose has been reported to bind and decrease absorption of salicylates, cardiac glycosides and nitrofurantoin. Psyllium may bind warfarin (e.g., Coumadin®). The clinical significance of these reports is not known.

Consumer Advice

Some people believe that toxic substances in the bowel will be absorbed into the blood if they are not purged each day. Others believe that constipation causes weakness, mental sluggishness and headache. Both of these are unfounded.

On a physiological basis, when a person has the urge to purge daily, and takes a laxative to accomplish this, he may be involved in a vicious cycle. The laxative causes a bowel movement. It may then take 2 or 3 days for the colon to collect enough stool to initiate another bowel movement, especially if a low residue diet is eaten. Failing to achieve this the next day, the individual feels he is constipated, and takes another dose.

Ritually taking laxative products may decline somewhat in the future as more and more young people are taught that daily catharsis is unnecessary. Also, the nation seems to be moving toward a more rational diet with increasing fiber content.

Bulk laxatives are indicated whenever a low-residue, constipating diet cannot be avoided. They are also indicated in physically inactive persons such as those who are confined to bed, and in those with diverticular disease. Representative examples of OTC products are listed in Table 2.

Bulk forming laxatives should be taken with at least eight ounces of

TABLE 2

Representative OTC Bulk Forming Laxatives

Cillium (Whiteworth)	Powder	Psyllium
Citrucel (Lakeside)	Powder	Methylcellulose
Cologel (Lilly)	Liquid	Methylcellulose
Effersyllium (Stuart)	Effervescent	Psyllium
Fiberall (Rydelle Labs)	Powder, Wafer	Psyllium, bran
Hydrocil Instant (Rowell)	Powder	Psyllium
Konsyl-D (Lafayette)	Powder	Psyllium
Maltsupex (Wallace)	Tablet, Powder	Malt soup extract
Metamucil (Procter & Gamble)	Powder, effervescent powder	Psyllium
Mitrolan (Robins)	Tablet, Chewable	Polycarbophil
Modane Bulk (Adria)	Powder	Psyllium
Naturacil (Mead Johnson)	Chewable cube	Psyllium
Pro-Lax (Vangard)	Powder	Psyllium
Perdiem (Rorer)	Granules	Psyllium
Reguloid (Rugby)	Powder	Psyllium
Serutan (Beecham)	Powder	Vegetable hemicellulose from psyllium
Siblin (Parke-Davis)	Granules	Psyllium
Syllact (Wallace)	Powder	Psyllium
V-Lax (Century)	Powder	Psyllium

fluid, to avoid esophageal, stomach and small or large bowel obstructions, and fecal impactions. Fruit juice or cola drinks can be used in place of water to improve the taste. One product, Citrucel, has apparently conquered the bad taste problem. It contains methylcellulose, is non-gritty, and is described by many as being comparable in taste to a glass of orange-flavored breakfast beverage.

Drinking 10 to 12 glassfuls of water each day, in addition to taking a bulk forming laxative, is one way to treat constipation. Most constipated patients do not drink enough water. Their body conserves liquid by reabsorbing it from the colon, thus making the fecal mass hard and difficult to move. A cup or two of warm coffee or tea, or even a full glassful of warm water (flavored with a drop or two of lemon juice, if desired) should be consumed each morning on arising. A full glass of water should also be drunk with each meal and after each urination.

Certain foods help promote laxation. These include fruits and vegetables, oatmeal, cracked-wheat bread, and bran. Affected individuals should eat a diet rich in these foods. They should likewise avoid items, such as cheese, which are constipating. Also, regular exercise and maintaining regular bowel habits helps combat constipation.

Bulk forming laxatives, like all other laxatives, should not be used for longer than one week unless recommended by a physician. The FDA/OTC advisory panel that reviewed laxative products indicated that some of the ingredients in bulk forming laxatives, especially those that are present at comparable levels in foods, may safely be used for longer periods. The time limitation for OTC use of one week is not based on toxicity of the ingredient, but on potential harm that can arise from the underlying condition. Constipation lasting longer than one week could be a sign of a more serious pathologic condition such as diverticular disease of the colon, irritable bowel, or cancer of the colon. Thus, a decision to use a product for longer than a week should be made by a physician. But, when the decision has been made in favor of chronic laxative use, the bulk forming products would be best. Table 3 summarizes important consumer advice about bulk forming laxatives.

TABLE 3

Consumer Advice

- This product promotes evacuation of the bowel by increasing the bulk volume and water content of the stool, and softening it.
- Do not use any laxative product when abdominal pain, nausea or vomiting are present, unless directed by a doctor.
- If you have noticed a sudden change in bowel habits that persists over a period of two weeks, consult a doctor before using a laxative.
- Bleeding from the rectum, or failure to have a bowel movement after using a laxative, may indicate a serious condition. Discontinue use and consult a doctor.
- Drink a full glass of liquid (at least 8 ounces) with each dose, and at least 8 glassfuls of liquid each day.
- Do not use this product for a longer period than one week except under the advice and supervision of a doctor.
- This product generally produces a bowel movement in 12-24 hours, but it may take up to 72 hours to get the first bowel movement.
- For products marketed as wafers and cubes: Chew these wafers (cookies) or cubes, and follow with 1-2 glassfuls of water.
- Eat foods that have a high fiber content, such as whole grains, bran, fruits and vegetables.
- Schedule time for a bowel elimination each day in the morning, and time for a regular exercise program.

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A public service of this publication

The "For Your Good Health" leaflet to the right is presented by the MPhA Public Affairs Committee. Members may use this patient education series as bag stuffers or newsletter material.

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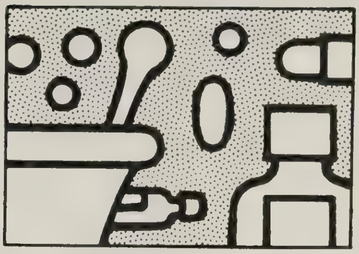
Things You Should Know FOR YOUR GOOD HEALTH



Prescription Medicines: Benefits & Potential Risks

Prescription medication can:

- Prevent disease
- Help cure disease
- Fight infection
- Relieve discomfort
- Speed recovery
- Alleviate pain
- Help avoid more expensive treatments and hospitalizations

But along with these benefits, prescription medications involve potential risks. For example, side effects are possible with any medication. Side effects depend on the type of medication and the person taking it. Learn about possible side effects before taking any medication. **ASK YOUR PHARMACIST** what to expect and report any suspected side effects to your physician. He may be able to prescribe a different medication for you.

Misuse or abuse of medications, whether accidental or deliberate, can be dangerous. For example:

- **Discontinuing too soon.** Don't stop taking your medicine because you're feeling better (or if it makes you feel worse). Follow your physician's and pharmacist's instructions.
- **Mixing with alcohol.** Some medications in combination with even a little alcohol can slow breathing and heart rate and dull reasoning ability. Other combinations may cause nausea, coma or death.
- **Not taking medication on time.** Skipping a dose or waiting too long between doses can make the medication ineffective. Taking doses too close together can result in an overdose. Some medications should be taken with meals; others without.
- **Taking too little or too much.** Too little can make the medication ineffective. Too much can cause an overdose.
- **Mixing with over-the-counter drugs.** Taking non-prescription drugs with a prescribed medicine can cause side effects.
- **Mixing with other prescription drugs.** Combining medications can cause problems. Tell your physician/pharmacist about all medications you're taking. Do not self-medicate.
- **Mixing with tobacco.** Smoking reduces the effectiveness of some medications. Combined with other medications, smoking can increase the risk of heart attack, stroke and other circulatory diseases.
- **Mixing with certain foods.** For example:
    - Dairy products can reduce effectiveness of some antibiotics.
    - Acidic drinks (fruit juices, soda, etc.) can cause some medications to be absorbed too quickly (or not at all).
    - Aged or fermented foods (cheese, wine, beer, salami, etc.) taken with some medications can cause headache, rise in blood pressure, even death.

Be sure you understand the label instructions and follow them exactly. If you have any questions about your prescription, **ASK YOUR PHARMACIST.** In this way you can reap the benefits of prescription medicines and avoid the potential risks.

© SPEA

The Pharmacist and Hospice

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IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

This is the first in a series of articles appearing in the next few columns dealing with specific problems encountered by health professionals involved with hospice.

MANAGEMENT OF NAUSEA AND VOMITING

Nausea and vomiting are common problems in hospice patients. Causes include motion sickness/vertigo, chemical or physical stimuli, emotional distress, gastrointestinal or gall bladder disease and infection. Greasy, fatty foods, alcohol and unpleasant odors also may stimulate nausea and/or vomiting. Drugs may also be the cause of nausea and vomiting, but some are more likely than others to be a problem, i.e. cancer chemotherapy drugs and narcotic analgesics.

Most episodes of nausea and vomiting are self-limiting and can be lessened by avoiding precipitating factors. However, nausea and vomiting cannot always be avoided and therefore palliative treatment with an antiemetic is often indicated. Antiemetics are often given by mouth, but once vomiting has occurred, may need to be administered parenterally or rectally.

Prescription antiemetics traditionally used have anticholinergic properties and/or block dopamine receptors in the central nervous system. These drugs include antihistamines, scopolamine, phenothiazines and trimethobenzamide (Tigan). Two of the newer agents used for prophylaxis or treatment of vomiting due to chemotherapy and radiation therapy are metoclopramide (Reglan) and dronabinol (Marinol). Dronabinol, the generic name for THC (active ingredient in marijuana) has recently been approved by the FDA for use in nausea/vomiting associated with cancer chemotherapy.

Patient Assessment

In evaluating the need for an antiemetic or for referral to a physician, the pharmacist must take several factors into consideration:

- The patient's age is important, since elderly or debilitated patients should be given smaller doses to start.
- A full drug history should be obtained in order to assess for drug-induced causes.
- The duration of vomiting, as well as vomitus content is important (i.e., fecal smelling vomitus is a sign of obstruction).
- Presence of other symptoms should be noted, i.e., abdominal pain, swelling or headache.

Available both parenterally (5 mg/ml) and orally (10 mg tablets and 5 mg/ml syrup), metoclopramide stimulates motility of the upper GI tract without stimulating gastric, biliary or pancreatic secretions. Cholinergic action on smooth muscle results in accelerated gastric emptying and intestinal transit. The antiemetic effect of metoclopramide is thought to be a combination of the antidopaminergic effect in the chemoreceptor trigger zone (CTZ) as well as the decreased sensitivity of visceral nerves that transmit afferent impulses from the GI tract to the vomiting center, and the peripheral effect on smooth muscle.

Onset of action is 30–60 minutes following an oral dose of 10 mg, 15 minutes after IM administration. Metoclopramide's effect persists for 1–2 hours following a single dose. The predominant route of elimination is the kidney, therefore a dosage reduction may be necessary in patients with renal disease.

Side effects are usually mild, transient and reversible following discontinuation of the drug, and most frequently are CNS. These include drowsiness, restlessness; less frequently seen are insomnia, headache and dizziness. Anxiety and agitation may be seen after rapid IV administration.

Extrapyramidal reactions may occur in all age groups, but are most common in children and young adults, as well as those receiving higher doses (i.e., 2 mg/kg) during IV administration. Such reactions consist of feelings of motor restlessness (akathesia) and have been shown to subside with a reduction in dose. These reactions usually occur within 36 hours after starting therapy and subside within 24 hours after discontinuation. Diphenhydramine and benztropine may be used as needed. Other parkinson-like symptoms including tremors, rigidity, bradykinesia occur rarely.

Dystonic reactions (involuntary movements of limbs, facial spasms, rhythmic protrusions of tongue, bulbar type speech, etc.) occur in <1% of patients receiving lower doses (30–40 mg daily), but 25% of younger adults (18–30 yrs) and 1.8% of older adults (>30 yrs) receiving higher doses (2 mg/kg/dose).

Tardive dyskinesia (manifested by ardouccal movements), which may be irreversible, generally occurs most frequently in the geriatric age group after long-term therapy (i.e., 1–4 years), after the drug has been discontinued.

Other adverse effects include constipation and/or diarrhea, occasionally urticaria, rashes, xerostomia, glossal and periorbital edema. Since structurally similar to procainamide, cross-sensitivity to metoclopramide is possible. Therefore, caution is advised in patients with procainamide allergy. Caution is also advised in patients with seizure disorders (lowers seizure threshold), children & young adults as well as those on antipsychotic or antidepressant therapy (increased risk of extrapyramidal reactions). Metoclopramide is contraindicated in patients in whom GI stimulation is dangerous (e.g., perforation or mechanical obstruction).

It is not clear whether metoclopramide is effective orally as an antiemetic. Doses for chemotherapy-induced vomiting are 2 mg/kg usually by IV infusion 30 minutes before administering the emetogenic drug, repeated twice at 2 hour intervals. If vomiting is suppressed, then 1 mg/kg every 3 hours for three additional doses may be used. An alternate regimen for less emetogenic drugs would be to use 1 mg/kg initially at 2 hours intervals, then 3 hour intervals as above.

The leading cause of death is living!

A Volunteer's Perspective

by Teresa Alpert

In my experience as a hospice volunteer for over five years, I have learned that the Pharmacist is an essential part of effective hospice care. The Pharmacist is the back bone to pain management and symptom control. One of the most important aspects to hospice care is that the patient be pain free. After that is accomplished then the hospice team (doctor, nurse, social worker, caregivers and pharmacist) can get on to other matters that need to be addressed. You can support the team by suggesting drugs that would enhance the quality of life for the person in pain. Unless the drugs being prescribed are understood they will not be used effectively. Six factors need to be known and shared with the hospice team:

1. Site of action
2. Duration of action
3. Dosage range
4. Symptom Response
5. Side effects
6. Interation

A review of the patient and of all his/her medications must be performed regularly and frequently. Treatment must be acceptable as well as effective and the dose of a drug may need to be either increased or decreased. Treatment must always be adapted to the patient's changing circumstances. When narcotics are prescribed, suggest something for constipation or nausea and vomiting. Below are some helpful hospice hints that are greatly appreciated by the patient and his/her caregivers.

1. Oral hygiene: Many of the drugs cause the patients mouth to become dry. You can offer lemon sticks and swabs, or crushed ice. Ask the patient if they can do their own mouth care. This will give the patient a sense of control. Chapped lips, bad breath and bleeding gums will make the patient very uncomfortable.
2. Skin care: Massage stimulates the skin and increases the circulation. This is an opportunity for some quiet time with the

patient. It also gives you a chance to see if the skin is red and irritated which may require further attention.

3. Medical Equipment: In addition to commodes, suggest that the caregiver purchase a deoderizer and place the commode in an area away from the bed. Using a commode is a statement that the patient is no longer able to do things the way he/her could do before. So be sensitive, offer a privacy screen and place the commode in another room when company arrives.
4. Follow-Up: Call the family or send a card when the person dies. You have been a very close provider. Everyday the caregivers have opened the bottles with your name imprinted. Ask them if they would like you to pick up any of the drugs or if they would like to bring them back to your store. This is the first step to completing the seperation from the loved one by giving away something that was once theirs.

At this point I would like to introduce you to S.H.A.R.E. Support Hospice Area Resource Exchange, Inc. S.H.A.R.E. is a non-profit organization established in 1983. The purpose of S.H.A.R.E. is to meet the urgent financial request of the hospice patient within 24 hrs., also to provide education, and refferal services to the community. All funds raised for S.H.A.R.E. are for direct patient care, there is no overhead or administration cost. Please consider S.H.A.R.E. as your charitable donation. All donations are tax deductible, but most importantly you will be helping those in need of your support. Make checks payable to S.H.A.R.E./ Support Hospice Area Resource Exchange, Inc. If you are interested in attending a workshop "This Business of Death & Dying" or want to make it available to your staff please write or call for an appointment.

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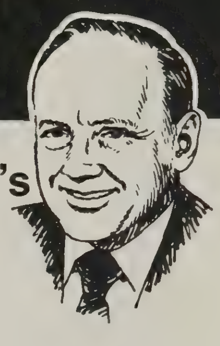
301-363-7569
Teresa Alpert Director

MP

'Tween Scripts

By Jake Miller, Pharmacist
Manager, Professional Relations
A. H. Robins Company, Inc.



Honoring Pharmacy's "Extra Effort" People

Again this fall, current year recipients of the A. H. Robins "Bowl of Hygeia" Award, selected by their peers through their professional pharmacy associations in the 50 states, the District of Columbia, Puerto Rico, and the 10 Canadian provinces were invited to be guests of our company for a special salute in our Richmond headquarters.

The four-day event included receptions and dinners, tours of our manufacturing and research facilities and a sightseeing trip to Williamsburg, the restored colonial capital of Virginia.

It was a desire to encourage pharmacists to take more active roles in community affairs that prompted E. Claiborne Robins, chairman of the board of A. H. Robins Company and a pharmacist himself, to establish the "Bowl of Hygeia" Award in 1958. The award provides special recognition to the men and women of pharmacy for their many and varied community services.

Some have served in their state legislatures and on city councils. Others have filled important positions on planning and zoning commissions and hospital, school and other boards. They have provided leadership for fund drives and countless special projects, and have participated in the work of youth organizations, civic clubs, churches and fraternal organizations. Perhaps a quarter of the 1,600 plus recipients thus far have headed their state or provincial pharmaceutical associations at one time or another.

The award is a handsome plaque featuring the Bowl of Hygeia cast in bronze. So that they may be recognized wherever they go, award winners are also presented lapel pins which are scale replicas of the plaque, and at any gathering of pharmacists, those wearing the pin form a proud "alumni" of previous recipients.

A. H. Robins is pleased to be able to assist state and provincial associations in recognizing these "extra effort pharmacists."

Jake Miller

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The interns tour the corporate museum at the Upjohn Visitor's Center. From left to right:
Allison L. Vordenbaumen, University of Texas at Austin
Mark B. Boeckmann, University of Illinois at Chicago
Heidi M. Blum, Wayne State University
Judith A. Shinogle, University of Kansas

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ANNUAL REPORT OF THE MARYLAND BOARD OF PHARMACY
1986–1987

In compliance with the provisions as set forth in the Health Occupations Article Section 12-205 of the Annotated Code of Maryland, this report is submitted to the Honorable William Donald Schaefer, Governor of Maryland, the Secretary of Department of Health and Mental Hygiene, Adele Wilzack and to the Maryland Pharmaceutical Association. This is the eighty-fourth report to the Governor and Secretary and the seventy-third report to the Association. The report covers the activities of the Maryland Board of Pharmacy for the period May 1, 1986 to April 30, 1987. This report is also being submitted to the McKeldin Library of the University of Maryland, the Enoch Pratt Free Library, the Department of Legislative Reference, the Hall of Records and the State Library.

MEETINGS

During the year the Board held seventeen meetings, five of which were held at the School of Pharmacy of the University of Maryland, for the purpose of conducting examinations for licensure of pharmacists.

OFFICERS AND MEMBERS

Anthony Padussis was elected President and Milton Moskowitz was elected Secretary-Treasurer of the Board. Dr. Moskowitz will begin to serve when Paul Freiman completes his term. In addition to the President, Anthony Padussis and Secretary-Treasurer, Paul Freiman, the Board consists of the following commissioners: Ralph Small, Steve Cohen, Leonard DeMino, Milton S. Moskowitz, Theodore Litwin, and William E. Adams. All the Commissioners are registered pharmacists in the State of Maryland with the exception of Mr. Litwin and Mr. Adams who are consumer (public) members of the Board.

PERSONNEL

The staff consists of Roslyn Scheer, Executive Director; Dee Moore, Office Secretary; Patricia Cockrell, Steno-Clerk; Peggie Lewis, Office Clerk and Elizabeth Rossi, part-time Office Secretary.

EXAMINATION

The Board conducted examinations for licensure of pharmacists during the year. They were held at the School of Pharmacy of the University of Maryland on June 24, 25, 26, 1986 and September 23 and 24, 1986.

The applicants who were examined in June of 1986 were licensed in July, 1986 which is in F.Y. 1987. There were one hundred and three applicants for the Board in June 1986. Ninty-one passed both the theoretical and practical portions of the examination and were licensed. Twelve failed the examination.

There was one candidate for reinstatement. He passed the examination and was reinstated.

There were twenty-three applicants for the Board in September 1986 (F.Y. 1987). Fourteen passed both the theoretical and practical portions of the examination and were licensed. Nine failed the examination.

Data relative to the June 1987 examination will be given in the next Annual Report.

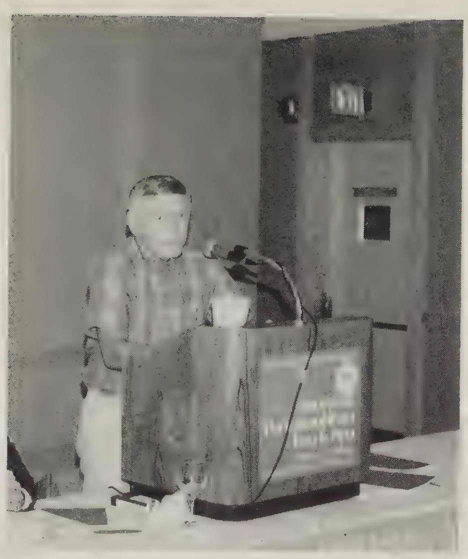
The pharmacist licensure examination is given in two parts consisting of the following:

Part I—NABPLEX
Part II consists of: Laboratory
Maryland Law
Federal Law

The NABPLEX and the Federal Law Exam are obtained from NABP. The Maryland Law Exam and the Laboratory Exam were compiled by members of the Board. The Laboratory Examination requires the compounding of four prescriptions per applicant. The following table shows the number of pharmacists who were licensed by examination during the past ten years.

YEAR	NUMBER OF PHARMACISTS
1977–1978	150
1978–1979	137
1979–1980	180
1980–1981	183
1981–1982	100
1982–1983	116
1983–1984	92
1984–1985	92
1985–1986	109
1986–1987	105

As in the past, many pharmacists applied for recip-



Paul Freiman delivers the official report of the Maryland Board of Pharmacy to the MPhA Convention and completes ten years of service as Secretary to the Board.

rocal licensure in Maryland in order to accept positions with their employers who have stores in Maryland.

In all cases, an applicant for reciprocal licensure must appear for a personal interview. The entire Board must act on whether or not to grant licensure to such applicants, who must sign an agreement to comply with Maryland's laws pertaining to drugs and pharmacy.

The following table shows the number of pharmacists granted licensure by reciprocity and the number who were certified to be licensed by reciprocity in other states during the past ten years.

Fiscal Year	Reciprocity	Certification
1977–1978	91	77
1978–1979	113	42
1979–1980	73	69
1980–1981	88	72
1981–1982	85	51
1982–1983	103	60
1983–1984	119	58
1984–1985	148	54
1985–1986	191	70
1986–1987	1,217	628

The table shows Maryland gained 589 pharmacists by reciprocity during the past ten years.

New permits to operate a pharmacy were issued to one hundred and twenty-five (125) firms as of April 30, 1987.

PHARMACY PERMITS

Location	1986–1987
Counties:	
Calvert	1
Carroll	2
Allegeny	3
St. Mary's	3
Queen Anne	2
Washington	1
Charles	1
Anne Arundel	4
Baltimore	21
Frederick	5
Garrett	2
Harford	2
Howard	6
Montgomery	12
Prince Georges	16
Somerset	1
Wicomico	2
Worchester	1
Cecil	1
County Total	86
Baltimore City	39
State-Wide Totals	125

Of the 125 locations that were issued permits, 10 were relocations and 2 were name changes. New permits were issued reflecting the changes; however, there were no changes in the permit numbers.

MANUFACTURERS PERMITS

New permits to manufacture drugs, medicines, toilet articles, dentifrices, or cosmetics as of April 30, 1987 were issued to four firms.

DANGEROUS DRUG DISTRIBUTORS PERMITS

The Board issued thirty (30) new permits to sell, distribute, give or in any way dispose of dangerous drugs as of April 30, 1987.

OTHER PERMITS

The total number of pharmacies in the State of Maryland is 1,085 and the total number of pharmacists is 5,100 as of April 30, 1987.

LEGISLATION

Only one bill which effects the profession of pharmacy either directly or indirectly was enacted by the 1987 Maryland General Assembly.

HB 91 (Health Care Providers—English Language Competency) requires applicants for a license to practice certain health occupations, including pharmacy, to demonstrate oral competency in English as a condition of licensing.

Graduation from a recognized English speaking undergraduate school after at least three years of enrollment, or from a recognized English speaking professional school is acceptable as proof of proficiency in the oral communication of the English language. To be licensed by the Maryland Board of Pharmacy applicants who did not graduate from these English speaking schools must pass the Test of Spoken English (TSE) given by the Educational Testing Service.

In addition, if any disciplinary charges or action that involves a problem with communication are brought against a licensee, the licensee must take and pass the TSE. HB 91 also authorizes the Board of Pharmacy to develop rules and regulations to implement a procedure for testing individuals who because of their speech impairment are unable to complete the standardized test of oral competency.

COOPERATIVE ACTIVITIES

The Board maintained cooperative activities with the State Department of Health and Mental Hygiene, the University of Maryland—School of Pharmacy, the Maryland Pharmacists Association, the Maryland Society of Hospital Pharmacists, the Chain Drug Group, City, County and State Police and all Boards and Pharmacy Schools throughout the country.

DISCIPLINARY ACTIVITIES

The Board of Pharmacy receives complaints from the public concerning problems with the Board's licensees. Other complaints were received from the Division of Drug Control, Medical Assistance Compliance Administration, State of Maryland Courts and other State Boards of Pharmacy. The wide range of complaints varied in severity. Listed below are statistics concerning the types of complaints for the period of May 1986 to April 1987.

miscellaneous*	26
mislabeled prescriptions	0
incorrect drug dispensed	9
generic substitution	2
wrong dosage dispensed	5
dispensing physicians	7
intent to distribute CDS drugs illegally	2
shortages of controlled drugs	2
communication	2
dispensing drugs without prescription	2
dispensing habits of pharmacist	27
TOTAL COMPLAINTS	84

* Complaints are on pricing, cleanliness, professionalism, prescription blanks and store hours.

Seven pharmacists were charged with violation of the pharmacy laws. No formal disciplinary hearings were held; five cases were resolved by Consent Agreements. Five pharmacists' licenses were suspended. Two pharmacists resigned their licenses with the posture of revocation. Some pharmacists were convicted of violating more than one statute. Listed below are the types of violations.

Is professionally, physically or mentally incompetent	1
Guilty of a felony	5
Disciplined by a licensing or disciplinary authority of any other state	1
Fraudulently or deceptively obtains a license	1

Two licenses which had been suspended and three revoked in a prior year were reinstated.

FINANCES

All funds of the board of Pharmacy are deposited to the credit of the Treasurer of the State of Maryland and disbursements covering the expenses of the Board are paid by voucher by the State Comptroller.

FINANCIAL STATEMENT

The Board of Pharmacy had revenues of $172,053 in 1985 and $187,005 in 1986. The Board of Pharmacy had expenditures of $146,573 in 1985 and $150,875 in 1986. The Board's budget is $151,974 for 1987 and $164,239 for 1988.

REGULATIONS

At this time the Board is in the process of proposing for promulgation or amendment regulations concerning:

1. Parenteral/Sterile Enteral Compounding
2. Reporting Pharmacists' Mailing Address and Location of Employment
3. Reinstatement of Expired Licenses for Pharmacists
4. Application Fee
5. Continuing Education
6. Waiver of Full Service Requirement for Recognized Pharmaceutical Specialties

BOARD RULING

On April 29, 1987 the Board of Pharmacy issued the following ruling on generic substitution.

Background

The Board of Pharmacy has received many inquiries from Physicians and Pharmacists concerning the meaning of Section 12-508 (b) (1) of the Health Occupations Article requiring a prescriber to state expressly that the prescription is to be dispensed only as directed. The Board of Pharmacy reviewed this carefully at its April 15, 1987 meeting and approved the following ruling authorized by Section 12-205 (a) (3) of the Health Occupations Article that allows the Board of Pharmacy to make rules and regulations that are necessary to protect the public health, safety, and welfare and that establish standards for practicing pharmacy.

Ruling

It is hereby ruled by the Maryland Board of Pharmacy that in Section 12-508 of the Health Occupations Article express intent by a prescriber to dispense a prescription under this section means that the authorized prescriber must, in his own handwriting, indicate on the face of the prescription that the prescription is to be dispensed exactly as written and no generic equivalent may be used by the pharmacist in filling the prescription.

Explanation

We trust that this ruling will clarify whether or not a generic can be substituted for a prescription dispensed in Maryland. Preprinted prescriptions that indicate no substitution and two line prescriptions indicating a generic can not be substituted will *not* require the pharmacist to dispense the brand name drug. If the prescriber writes "dispense as written", "do not substitute" or other language clearly indicating this, then the pharmacist must dispense the brand name drug.

SECRETARY-TREASURER'S MESSAGE

In 1987, the Board continued its excellent relationship with the Department of Health and Mental Hygiene. The cooperation and courtesy extended to the Board of Pharmacy by all members of the Department is appreciated by all the Board members.

Again the Board must commend our Executive Director, Roslyn Scheer, for her continued excellent management of the Board's business. Through her efforts the Board continues to operate smoothly and efficiently. In addition, the Secretary-Treasurer must commend our excellent secretaries Dee Moore, Pat Cockrell, and Peggie Lewis for their excellent work and cooperation. In addition, we welcome our newest secretary—Elizabeth Rossi.

All of the Commissioners actively participated by serving on various committees appointed by the President, attending numerous meetings throughout the State, and being available for consultations and special meetings when necessary.

Since my term on the Board expires in 1987, this will be the last annual report that I will be submitting. During my ten years I have seen the Board of Pharmacy progress from a little recognized agency with a pitifully small budget, to a viable Board able to perform its assigned tasks in a timely manner. I, along with all those involved, take a measured amount of pride in the achievements and growth of the Board of Pharmacy. I am sure that the Board will continue toward the goal of excellence in serving the citizens of Maryland by assuring them that pharmacy services provided will meet the highest standards. I thank you for the privilege of serving and look forward to a continuing close relation with the Maryland Board of Pharmacy and the profession of pharmacy.

Respectfully submitted,
Paul Freiman
Secretary-Treasurer

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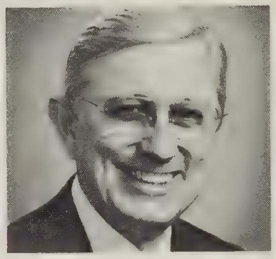
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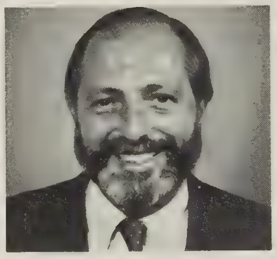
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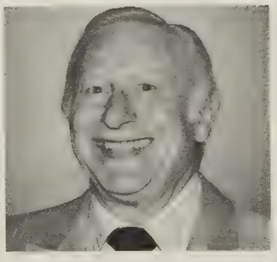
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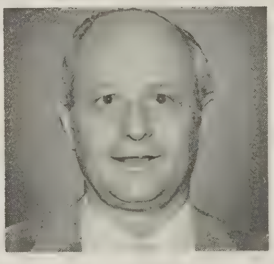
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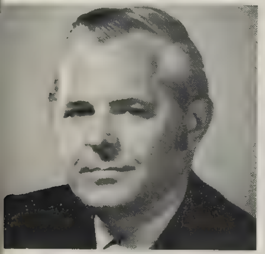
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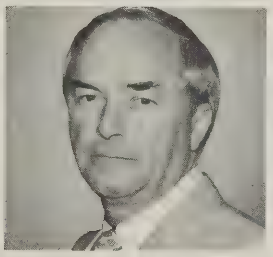
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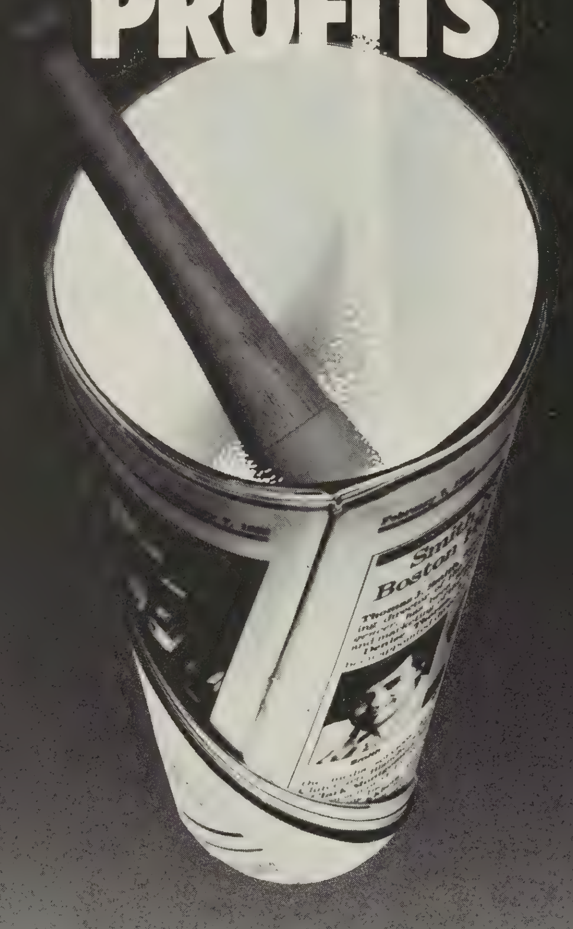

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More on Mail Order—A Commentary

by Jim Dickinson

Pharmacy according to Medco. At the outset of this latest of many Dickinson writings in mail-order pharmacy, let me make it clear that I am not opposed to mail-order—I am just skeptical. Mail-order worries me because there is no pharmacist-patient relationship, and I believe in those, even though some pharmacists are rotten at them.

My worries—and the worries of a growing number of legislators at both the state and federal levels—are heightened by the testimony in August at a Senate Governmental Affairs subcommittee hearing chaired by Senator Jim Sasser (D-TN), and by what came in my mail shortly afterward.

Medco Containment Services, Inc., owner of National Rx Services, was the focus of the hearing, which dealt with complaints by a panel of three former employees (all registered pharmacists), and with a complaint by a former patient who was dispensed Coumadin instead of Corgard.

Basically, the former Medco pharmacists, all of whom resigned voluntarily out of conscience, complained about Medco's high-volume quota system (54 Rxs per hour, six-plus hours per day), the 15-cents-per-Rx monthly bonus paid for Rxs averages exceeding 50-per-hour, the high levels of misfills by technicians (5% of all Rxs), and their inability to reassure themselves that the speed of the filling line could not cause *them* in their last-check responsibility to mail out death instead of therapy.

The pace of Medco's production line was "suicidal," they complained.

Mrs. Winifred Owen, of Virginia Beach, Virginia, testified that after her close call (she referred the different-looking tablets to her neighborhood pharmacist), she had quit her federal employee benefit Blue Cross/Blue Shield mail-order option, to pay full price at the local pharmacy. "I'm not ready to die yet," she told the *Washington Post*.

Medco was highly indignant about all these dreadful slurs. Its chairman, Martin Wygod, challenged the anonymity that the subcommittee had given to his former employees (they testified from behind a screen), and questioned their motives ("Are they disgruntled former employees? Are they now affiliated with Medco's competitors in the retail market? Do they have a financial interest in undermining Medco's reputation?")

As the agent who brought these pharmacists to the subcommittee, I am the one who initially guaranteed them anonymity—and the subcommittee staff agreed with me, after being introduced them. These pharmacists had seen enough of the unwholesomely cozy relationship between their state pharmacy board and their Medco bosses to be terrified for their licenses.

And, indeed, one state pharmacy board exec who has a major Medco facility in his state told me that, at least so far as he was concerned, "Medco is wonderful." The company is so cooperative, unlike independent pharmacists who often resent being inspected, and give inspectors a hard time.

And another board exec was alleged by a Medco pharmacist to have refused to conduct a snap inspection based on her long, anonymous complaints because (a) the board doesn't act on anonymous complaints, and (b) anyway, he would have to alert Medco to the inspection first, for "security reasons."

Is it any wonder my anonymous witnesses were slightly paranoid? As for who was paying them to tell lies about innocent Medco, one of my informants, offered $100 by me to critique Mr. Wygod's subcommittee testimony (which I sent her), completed the chore and wrote: "I wish to donate my $100 back to the cause at hand."

(Let me make an open invitation to all pharmacists at this point. If you know of a similar public safety hazard in pharmacy to the one described here, write me at P.O. Box 848, Morgantown, WV 26507-0848, or call on your nickel 304-291-6690, and I will provide the same anonymity guarantees as I did for the Medco pharmacists.)

To wrap up, the critiques my Medco pharmacists made of Mr. Wygod's written testimony have been (anonymously) turned over to Senator Sasser's committee. They describe that testimony as filled with falsehoods, and I believe there will be another hearing, to force testimony from the company *under oath*.

Other mail-order companies testified at the hearing, too. They told a more believable story. For example, instead of 54 Rxs/hour quotas and bonuses, the technician Rx mixups, Thrift Drug's Express Pharmacy Service testified that it is striving for a modest 30 Rxs/hour "goal" and every one of its Rxs is checked by at least two registered pharmacists.

If mail-order pharmacy can be practiced soundly (as the Veterans Administration and AARP seem to), I think this may be a way to do it. I have asked Thrift to let me bring my ex-Medco pharmacists in for a look.

I'll keep you posted. It's public health, safety and service that we're all interested in.

This feature is presented on a grant from G.D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G.D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G.D. Searle & Co.

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LETTERS

Dear Mr. Banta,

The Maryland Nurses' Association, Impaired Nurses' Committee, was pleased to see the article co-authored by the Executive Directors of the Pharmacy and Nursing State Licensing Boards titled "Licensing Boards and Impaired Professionals" in the June, 1987 issue of the Maryland Pharmacist. There is, however, a very active Impaired Nurses Committee and nurses in Maryland do have an Impaired Nurses Program. The purpose of this letter is to provide an update for you and your readers on the Maryland Nurses Associations' Impaired Nurses Committee's activities and the MNA Program for the Impaired Nurse.

In January, 1986, the committee began devising a new type of program based in principle on a nondirect intervention program approach. Having established this focus, we now have a nondirect intervention program with the following components.

1. Resource and Referral List. The committee developed this list which contains a broad range of information such as: identification of a contact person, a nurse, with each treatment source cited; a listing of committee members who are available for clarification, networking, etc. Information on this list can be obtained by calling MNA Headquarters at 242-7300. Copies have been sent to all resources identified, including the State Board of Nursing.
2. Educational and consultation were two services requested by those completing surveys sent to all employers of nurses in Maryland and Nurse Administrators of Treatment Centers for Chemical Dependency. These surveys were conducted by the committee in April, 1986 and during the winter of 1987; respectively, Committee members may provide some of nurse services, recommend the most appropriate resource to provide a particular service, and facilitate linkage with the resource. Members have also reviewed educational materials and see this as an ongoing committee function. A video has been selected for educational and consultative purposes.
3. Networking with other professional groups, professional associations and agencies and linking nurses with nurses is ongoing and seen by the committee as an essential activity. Monthly meetings are held between chairs or their representative from impaired professional programs; e.g. physicians, pharmacists, social workers, lawyers, dentists, etc. An all day workshop in the Impaired Professional held April 10, 1987 is one example of an outcome resulting from inter-disciplinary discussion. There will be another in the spring of 1988. The Impaired Nurse Committee encouraged the development of a nurses support group "Nurses Recovering Together" and also actively fosters nurse to nurse contact. Publicizing this support group's existence, as well as encouraging the development of other groups so that this type of resource is statewide, is an ongoing committee commitment.
4. Research and program evaluation are viewed as important components of this non-direct intervention program. The surveys provided a picture of the problem and have assisted in the identification of program components. Follow up studies will assess effectiveness of program components and identify future needs.
5. Committee composition. The executive director of the State Board of Nursing, a recovering nurse, a nurse educator, a nurse administrator, nurses in a variety of practice and work settings who have an interest and/or experience in treating chemical dependency and/or psychiatric illness are represented on the Impaired Nurses Committee. This variety offers a depth and quality we feel essential for a well rounded program. We are seeking a nurse researcher.

Sincerely,
Marie McCarthy
Chairperson
(301) 233-3342

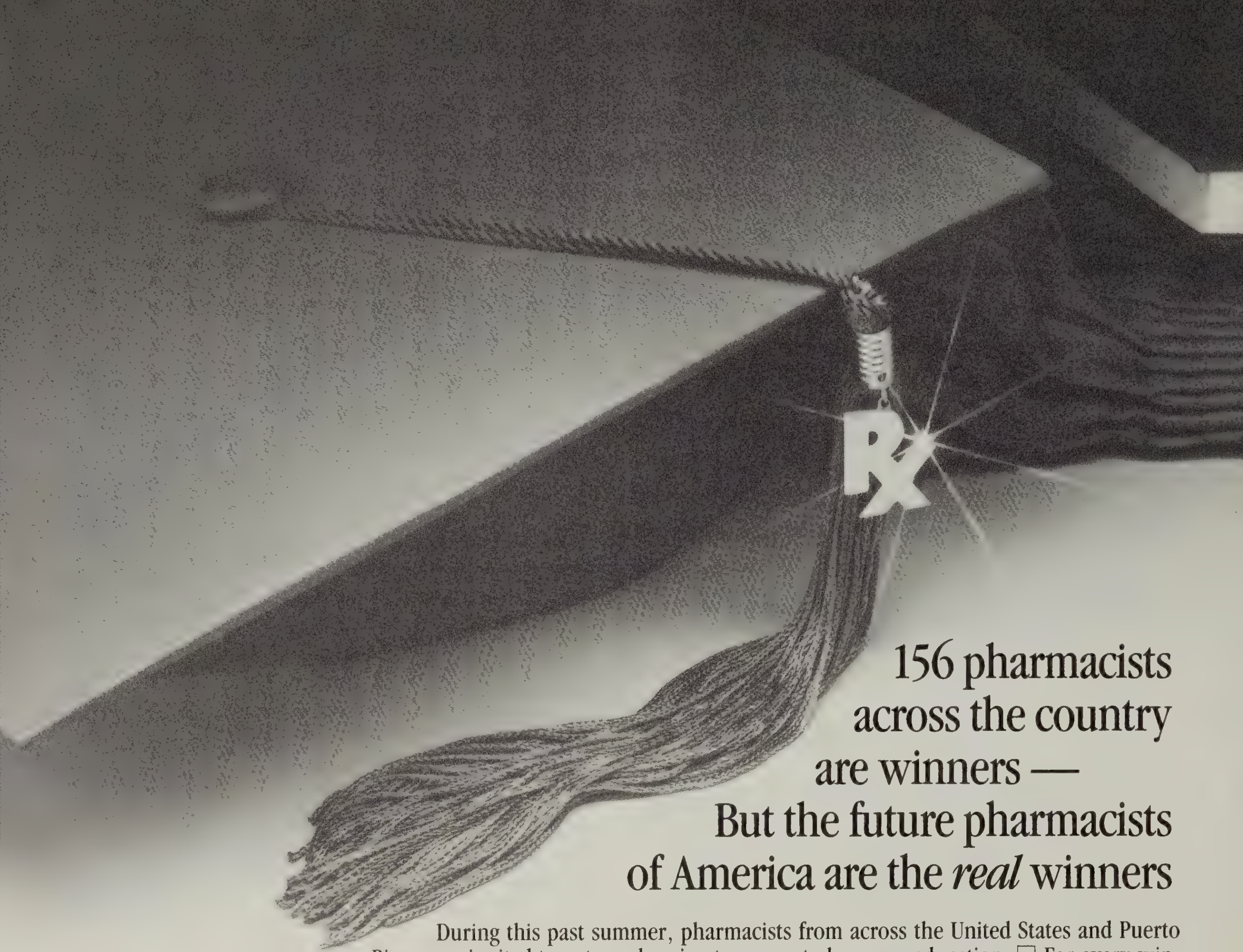
Dear Dave:

On Thursday evening November 19, 1987 the School of Pharmacy will conduct on orientation meeting for potential preceptors for the Professional Experience Program (PEP).

PEP provides experiential training in a variety of sites throughout the state. These are learning experiences. The relationship between extern and preceptor is primarily that of student/teacher. Two major criteria for selection are an interest in teaching future colleagues the practice of pharmacy and a pharmacy practice fitting to serve as a role model for students to emulate upon graduation. Selection is also based upon the need in a particular geographic area.

Interested pharmacists can contact me at the School of Pharmacy (328-7118) for further information.

Cordially,
Marvin L. Oed, Pharm.B.S.
Clinical Assistant Professor, and
Director, PEP



156 pharmacists across the country are winners — But the future pharmacists of America are the *real* winners

During this past summer, pharmacists from across the United States and Puerto Rico were invited to enter a drawing to support pharmacy education. ☐ For every winning entry — 156 in all — Burroughs Wellcome Co. pledged to donate a $500.00 scholarship to a pharmacy school and a matching $500 grant to one of six national pharmacy associations of the winner's choice. ☐ To everyone who entered the drawing, thank you very much. And to the following winners, our most sincere congratulations:

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In the War Against Drug Abuse—What Can We Do?

by Mark L. Hayes

Everywhere you turn, you hear about the problem of drug abuse in our country. Nancy Reagan, in a speech delivered to the World Affairs council in June of 1986, said that "there's a drug and alcohol epidemic in this country and no one is safe from its consequences." And an epidemic it is.

A Billion Dollar Industry

Americans spend $50 billion a year on marijuana, smoking 31 tons of the substance each day. The use of cocaine among high school students has risen to 5.8%, an all-time high. An amazing 35% of high school seniors use stimulants. Of these, 1% use them daily. Ninety-three percent report trying alcohol, and 5.8% report being daily users. The ratio of seniors who report drinking five or more drinks in the prior two-week interval is at a shocking 41%. The use of heroin has remained steady with 1.2% reporting experience with the drug. Nine percent report experience with opiates other than heroin. However, these statistics can be misleading, considering that 15% of today's students leave school before their senior year.

It usually starts with cigarettes, which serve as the first break from parental guidance. After cigarettes, alcohol is usually the next step on the experimentation field. From there, an astonishing 95% experiment with marijuana. Then, it seems, the sky's the limit as they begin to abuse the "street drugs"—cocaine, LSD, and various prescription drugs. According to the National Institute on Drug Abuse (NIDA), "of kids who smoke cigarettes, 81% will try marijuana, and of those who try marijuana, 60% will then try other drugs."

The most staggering problem is cocaine. Americans spend $39 billion annually on the substance. It is estimated that 22 million Americans have tried the drug. Of these, at least 10 million use the drug monthly. An incredible one million suffer from chronic addiction. The members of the "baby boom generation," the now so-called "yuppies," comprise the largest group of users.

Americans feed $80 billion into the illicit drug market each year, not including alcohol. Amazingly, this amount is four times the combined OTC and prescription drug markets.

Pharmacists Against Drug Abuse

Many pharmacists are getting involved in the war on drug abuse. They are meeting with parents, youth, and members of their community to combat the problem. The pharmacist is the most accessible health professional. This accessibility, combined with extensive education, puts the pharmacist in a perfect position to serve as a drug abuse counselor.

One way in which you can get involved is with the Pharmacists Against Drug Abuse Foundation (PADA). Founded in 1982, PADA is an organization of pharmacists working hard to fight drug abuse.

The organization was an inspiration of Jack B. O'Brien, then president of McNeil Pharmaceutical, following a meeting at the White House with approximately 200 business executives whom Mrs. Reagan wanted to inform about the seriousness of the drug abuse problem in this nation. Shocked by what he learned at that meeting, Mr. O'Brien promised Mrs. Reagan that his company would establish a drug abuse program. He assigned Herbert W. Browne the responsibility of developing such a program with the suggestion that community pharmacists should be a key ingredient.

While meeting with the National Federation of Parents for Drug-Free Youth (NFP) and the Parent Resources Institute for Drug Education (PRIDE), an idea was proposed. If an educational program could be devised that would make drug abuse information widely available to parents, and if these parents would unite in the community to develop programs to curtail drug abuse, the program should be successful. The result: Pharmacists Against Drug Abuse.

Pharmacists—The Active Ingredient

Pharmacists are getting involved for many reasons. First, they have a vast knowledge about drugs and their pharmacological effects on the body. Second, they are accessible, since fifty to seventy thousand people walk through the doors of a pharmacy each day. Third, pharmacists care about the communities they serve and about maintaining a safe pharmacy environment. When drug supply on the street runs low, drug addicts must turn to the pharmacies. This phenomenon translates into an increase in theft and endangers the lives of pharmacists.

What does PADA do? PADA provides education for pharmacists through a 50-page booklet entitled "A Pharmacist's Guide to Drug Abuse." The booklet contains information about many street drugs, including marijuana, cocaine, LSD, and PCP, and about tobacco, alcohol, and abuse of prescription drugs.

Pharmacists may obtain a brochure entitled "The Kinds of Drugs Kids Are Getting Into" free of charge from their local wholesalers. This educational brochure is for parents and comes with an easel for display on the pharmacist's counter. Window signs and pocket-savers that say "This is a place where parents can learn about drug abuse" may also be obtained.

PADA also hosts training sessions to aid pharmacists in anti-drug abuse speeches in their communities. Participants receive speaker kits, containing slides and two sample speeches, one for parents and one for young people.

Since its launch on November 15, 1982, approximately 15 million brochures have been distributed. PADA has hosted over thirty training sessions in as many cities. Herb Browne, president of the Pharmacists Against Drug Abuse Foundation, says that attendance at the sessions averages over 100 pharmacists. This computes to over 4000 pharmacists who have benefited from the sessions. Literally hundreds of speeches are now given each month by pharmacists to parents groups, civic and religious organizations, students, etc. But there is still much to be done.

The PADA program has also been launched in foreign countries. In 1985 the program was launched in Italy and is still growing today. Other PADA programs have been launched in South Africa, Ireland, England, and Canada, with more planned in other countries.

To Find Out More

On October 31 at the American Pharmaceutical Association Midyear Regional meeting in Baltimore, MD, PADA will present a one and one-half hour program to pharmacists and students to help them get involved. Here you can learn what pharmacists all across the country are doing to curb the abuse of drugs. The program will feature speakers who will present an overview of drug abuse and discuss specific agents. Pharmacists can also receive continuing education credit for the session.

Now is the time to do your part in the battle against drug abuse.

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Zidovudine (Retrovir) Approved by FDA to Treat AIDS

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School of Pharmacy
Northeast Louisiana University
Monroe, LA 71209-0470
(318) 342-3065

(At press time, we learned that B.W. is placing Retrovir in general distribution effective September 15, 1987)

Zidovudine (Retrovir by Burroughs Wellcome; formerly named azidothymidine [AZT]) is the first drug approved by the Food and Drug Administration (FDA) to be used in the treatment of certain types of AIDS patients. However, now Burroughs Wellcome must try to meet the demand for the drug and it is anticipated there will be a limited supply for the immediate future. Present production capacity only will meet the needs of approximately 15,000 patients with projections of increased production for approximately 30,000 patients by the end of the year. Not only is the drug in short supply, but it is extremely expensive—estimated to cost $10,000 per patient a year. The cost to pharmacies is about $188.00/100 of 100mg tablets. The average patient cost of the drug is $25.00/day because most patients take two tablets every four hours.

A special panel has been organized by the Infectious Disease Society of America in an attempt to ensure that patients will receive a continuous supply of zidovudine (Retrovir). Burroughs Wellcome has also established a unique Retrovir distribution system to minimize inventory holdings of the drug. The process to obtain Retrovir starts with the physician submitting an enrollment application for the patient to be considered as a candidate. These applications are obtained by calling Burroughs Wellcome's Retrovir Center at (800) 843-9388. Medical specialists then review the application against FDA-approved indications. The center will notify the physician (usually within one week) if the patient meets the criteria and if there is a sufficient supply of Retrovir. The physician is issued a patient enrollment number (once the patient is enrolled) which must be on all Retrovir prescriptions to be filled by a pharmacist.

The Retrovir Center will notify the physician if their patient meets the criteria but there is an insufficient supply of Retrovir. The center will recontact the physician when the Retrovir supply is sufficient to supply the patient. For those patients who do not meet current criteria and are turned down, the physician is urged to reapply if the patient's condition changes. Packets of information will be provided to physicians and pharmacists. The physician packet includes details of the distribution program, information about Retrovir, patient enrollment forms, and information for the patient. The pharmacist packet is similar and includes information on how a prescription for Retrovir can be filled.

When a pharmacist places an order for a patient, a one-month supply of Retrovir will be supplied to the pharmacy. However, it will not be possible to obtain additional Retrovir with that patient's enrollment number for 25 days. If the physician has ordered refills, then the pharmacist can reorder Retrovir each month without calling the center. The center will monitor ordering patterns at pharmacies.

About 4300 patients currently are receiving Retrovir free because of the investigational new drug (IND) program. These patients will not go through the enrollment process but will entered automatically into the system with their IND protocol number. These patients will also be informed when they receive their last month's supply of free Retrovir and provided information on obtaining the drug from their pharmacy.

Fortunately for our profession of pharmacy, a number of pharmacists are only taking moderate markups on the drug. Some pharmacists are selling the drug at cost to needy patients. Our profession should salute these colleagues who are currently exercising such a humanitarian spirit.

AIDS Hotlines

The AIDS epidemic has resulted in the establishment of a number of "hotlines." These hotlines usually are two types: crisis or counsel/referral. Although it is desirable for hotlines to be staffed by qualified personnel, such may not be the case because many staff personnel are dedicated trained volunteers.

The Public Health Service (PHS) AIDS hotline has two components. The first component is a (800) 342-AIDS number which consists of a preliminary tape-recorded introduction that directs callers to the second component of telephone operators who provide further information and referrals. It should be noted that the PHS hotline is not a crisis line, but primarily a resource for information and referral.

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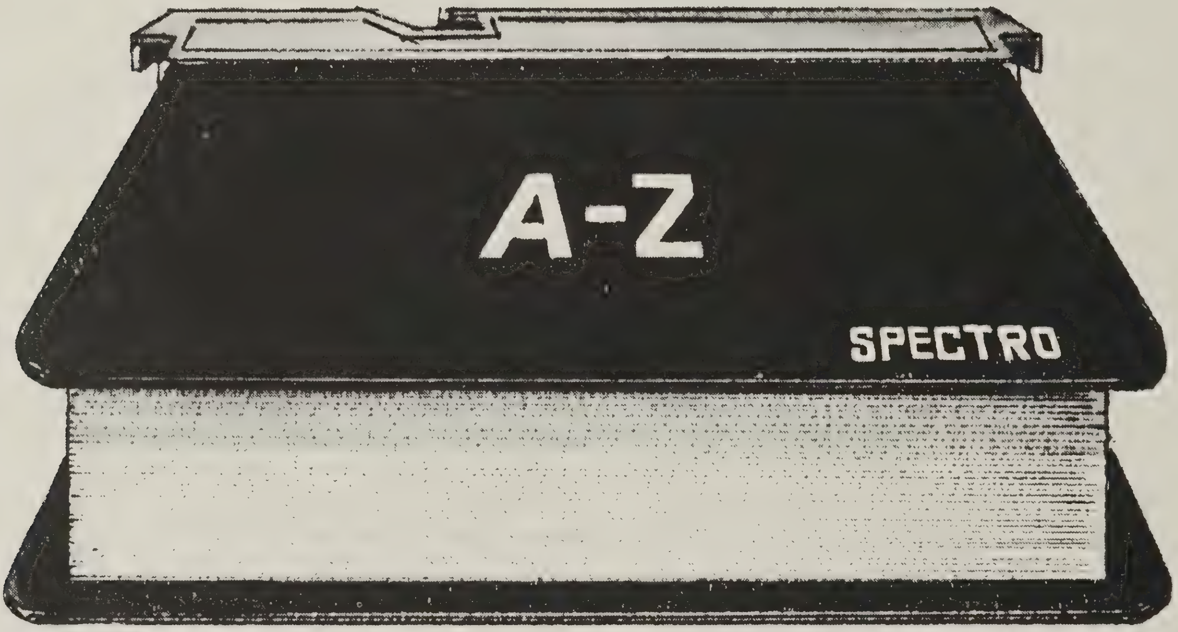

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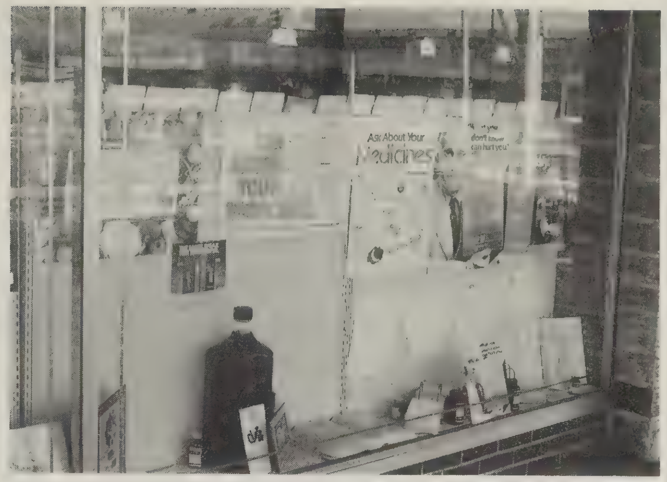
SPECTRO INDUSTRIES

Executive Director David Banta (left) presents Pharmacy Student Raymond Palasik (right) with a scholarship check. The MPhA scholarship program is designed to assist students during their P.E.P. rotation.

Roslyn Scheer, Executive Director of the Maryland Board of Pharmacy discussed the issue of extended or emergency pharmacy hours with members of the Association at the annual Convention.



Nick Lykos Pharmacy in Timonium uses a window display to highlight the on-going public service campaign "What You Don't Know *Can* Hurt You," sponsored by MPhA, the USP and WBAL-Radio and Television.

Bruce Greenberg, Vice President of the Student Chapter, delivered the Academy of Student Pharmacists' report to the MPhA Convention.

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Hotline for Pharmacists Rehabilitation Committee (301) 727-0746

FDA Hotline for AIDS 800-342-AIDS

Hotline for impaired Physicians (301) 727-0120

Hotline for impaired Dentists (301) 964-2275

A Pair of Whitehall Tatum Show Globes for sale with metal brackets. Call 433-9049.

The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

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calendar

Oct 9–11—MSHP ANNUAL SEMINAR—WILLIAMSBURG, VA
Oct 18–23—NARD Convention
Oct 23–26—MPhA Trip to Nassau, Bahamas
Oct 23–25—Post NARD Convention side trip to San Francisco
Oct 25–Nov 1—APhA Midyear Meeting, Baltimore, MD
Jan 17–24 (88)—MPhA Trip to Curacao in the Caribbean

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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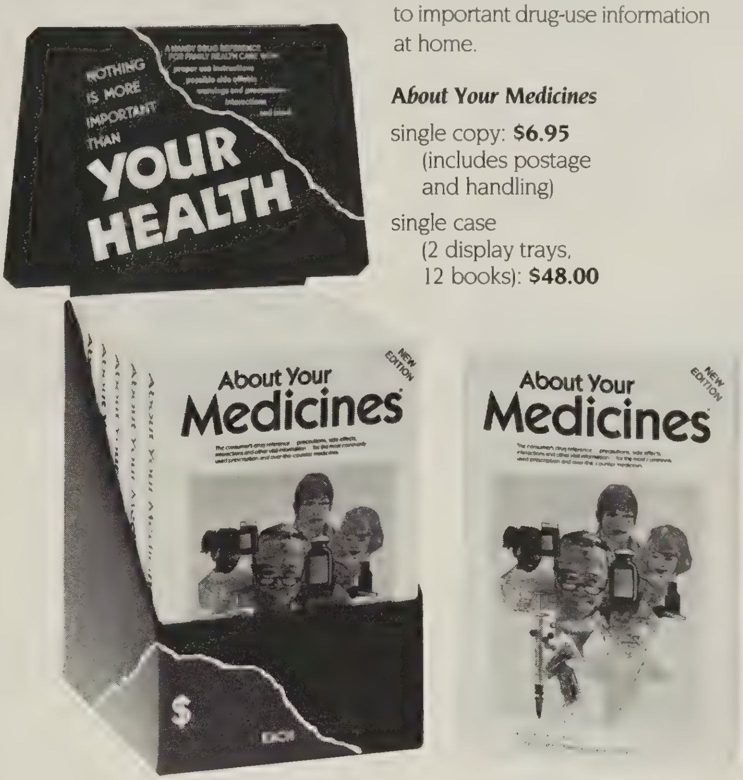

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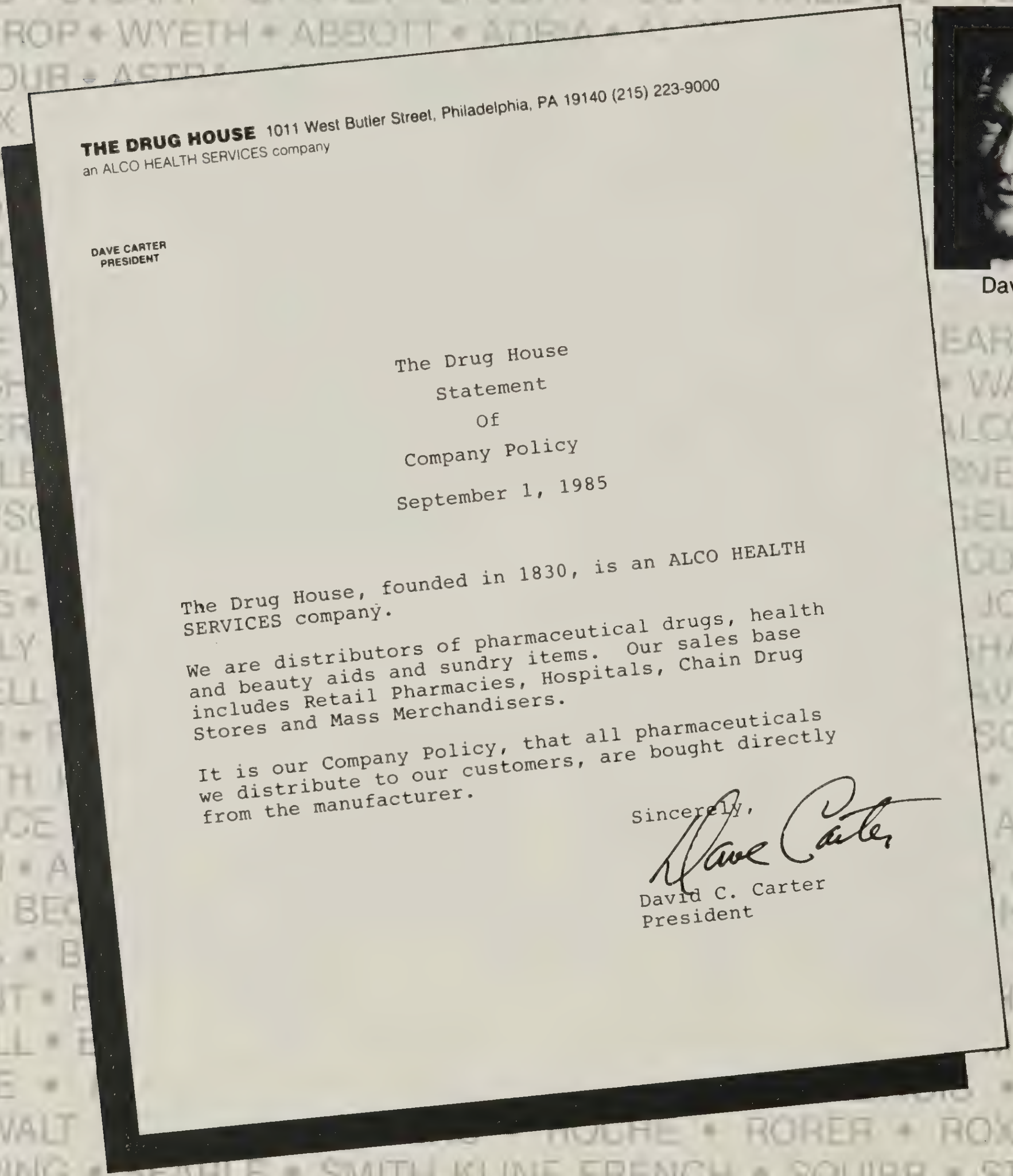

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PRESIDENT

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Statement
Of
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September 1, 1985

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Sincerely,

Dave Carter

David C. Carter
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David C. Carter,
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THE
MARYLAND
PHARMACIST

Official Journal of
The Maryland
Pharmacists
Association

November, 1987
VOL. 63
No. 11

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—J. Richard Wuest

The Pharmacist and Hospice—Management of Nausea and Vomiting

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Guidelines on Nurse Dispensing in the Absence of a Pharmacist

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PRESIDENT'S MESSAGE

One of the most volatile and changing sectors of national economy in recent years has been the Health Care Industry. There has been a significant change in the roles of the various professions. We have seen an erosion in the influence of the medical profession, where they were once dominant in setting the direction and course of the Health Care Industry, now physicians assistants, nurse practitioners, pharmacists and other professionals are expanding the scope of their professional practice. This trend will continue in the coming years and the once clear dividing lines between professions will blur even further.

There has also been a shift in the reimbursement of pharmacy for its services. Where individual consumers and a few pharmacy card plans once comprised most of our patrons now large insurance companies, HMO'S and possible in the near future, the federal government and its catastrophic Medicare drug bill will control our financial compensation. With the concentration of our payors into a few large groups there will be increased emphasis on cost containment measures, such as capitation programs, to hold down the costs of pharmacy services.

As the title of the Bob Dylan song states, ''The Times They Are A Changing'' and continued change is inevitable. But with change also comes opportunity. We have a chance to continue to grow and diversify within our profession if we speak in large numbers in a unified voice. Your input in conjunction with the opinions of your colleague will make pharmacy stronger. Now is the time for members and non-members alike to get off their apathy and become an active participants of their local and state pharmacy organization. Your professional and economic future is too important to be delegated to others. Become the master of your own destiny. Join Now!

Lee Ahlstrom, P.D.

PRESIDENT

CONTINUING EDUCATION FOR PHARMACISTS

VOL. IV, NO. 10

The Rx-To-OTC Shifts: Whys and Wherefores

by Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology
and Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

Goals

The goals of this lesson are to:

1. review the reasons why certain Rx drugs have been shifted or may be shifted to OTC status;
2. discuss information to pass along to consumers who are interested in knowing why these shifts are being made; and
3. describe the pros and cons of the "third class" of drugs.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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MERRELL DOW PHARMACEUTICALS INC.

Objectives

At the conclusion of this lesson, participants will be able to:

1. list specific drugs that have been shifted from Rx to OTC status;
2. identify current Rx drugs that have been suggested for possible shifting in the future;
3. state the criteria for a drug to be eligible for OTC status;
4. demonstrate an understanding of the projected economic impact on manufacturers, pharmacists and consumers for having an increased number of Rx drugs shifted to OTC status; and
5. select specific points of pharmacologic, toxicologic and therapeutic information about OTC drugs that were formerly available only on Rx.

Background

The OTC review process has spawned an enlarging nonprescription drug market.

Today, more than ever before, OTC drugs are potent and reliable. The overwhelming majority of them have undergone extensive testing to prove their safety and effectiveness for intended uses.

And American consumers are responding by spending an estimated $12 billion dollars annually. A World Health Organization survey reported that at least 40 million Americans take an OTC drug on any given day.

Part of the current trend is due to the large number of OTC drugs that formerly required a prescription for purchase. Nearly 20 such drugs have been shifted to date, and another 30 or more have been ticketed for possible OTC status.

Several factors are responsible for this, and they are not necessarily related to the FDA's OTC review process. Increasing pressure on the entire health care industry to become more cost-effective is the leading factor. Health care costs currently account for more than 10 percent of the GNP, and have increased at a rate far exceeding other segments of the economy.

A second important factor is a growing interest on the part of consumers to become independent and to take care of themselves. A third contributing factor is the discovery by drug manufacturers that the market potential for OTC products far exceeds that of prescription sales.

This activity could pose a potential problem for pharmacists who once supplied the majority of OTC products. Now they account for approximately 40 percent of OTC sales. And each time a prescription drug is shifted to OTC status, it is one less drug for pharmacists to exclusively distribute.

However, this does not have to be viewed negatively. As with any problem, it could be an opportunity for enterprising pharmacists since they can sell more of these products based on their own professional advice rather than having to wait for the next prescription to come by.

The Legislation

Before the 20th Century, there were few restraints on the sale of medication. But in 1906, Congress passed the **Pure Food and Drug Act** in an effort to protect the public against unproven and/or unsafe drugs. The Act also created the Bureau of Chemistry, which was the predecessor to the current Food and Drug Administration. Since its enactment, the original Act has been amended significantly. Important and relevant dates of revision are 1938, 1951 and 1962.

In 1938, Congress enacted the **Federal Food, Drug, and Cosmetic Act.** This required that manufacturers of drugs which are shipped in interstate commerce establish safety, and properly label the drugs. The Act specifically demanded adequate instructions for use in the labeling. Drugs which were considered safe for self-administration (OTC status) were also to be labeled with instructions for safe use by consumers.

While the 1938 Act clarified many issues omitted from the original law, there were still unanswered questions. For example, there was no clear delineation separating drugs that required a prescription from those available without one. While the **Harrison Narcotic Act** of 1914 required a prescription for all opium and coca leaf derivatives, there was no absolute demarcation for non-narcotic drugs.

There was also confusion regarding how much and what type of information pharmacists should impart to a patient when prescriptions were dispensed or OTCs were sold. In fact, FDA's decisions on prescription/non-prescription status of a drug were inconsistent and difficult to interpret. Whenever a drug was to be shifted from Rx to OTC status, it was usually at the initiative of its manufacturer.

To correct these deficiencies, the **Durham-Humphrey Amendment** to the FDA Act was passed by Congress in 1951. This legislation clearly separated drugs into one of two categories: prescription and non-prescription. It required that prescription drugs display the "federal legend" ("Caution: Federal law prohibits dispensing without a prescription."), and that prescription drug packages contain an insert with specified product information for the health professional.

Then, in 1962, the **Kefauver-Harris Amendment** to the Act was legislated. This required that manufacturers prove their products were effective to the satisfaction of FDA, rather than to the satisfaction of the medical profession, as well as being safe for use in humans. It also established the monumental review of non-prescription drug products which is what triggered the current Rx-to-OTC shifts.

The task of determining potential drugs for OTC shift was assigned to a group of advisory panels. These OTC panels consisted of health professionals, scientists, consumer representatives, and manufacturer representatives, who recommended the shifts to FDA based on a thorough evaluation of the literature. Thus, FDA's decisions to shift Rx drugs to OTC status are based on sound scientific evidence that the products can be safely used for self-administration without professional supervision.

The first FDA advisory panel to recommend a change in status was the one which reviewed nighttime sleep aids. In 1975, this panel found sufficient evidence of safety to shift diphenhydramine to OTC availability, and to change the dosage of doxylamine to be able to market them OTC as nighttime sleep aids. While FDA originally disagreed with the proposal, it later changed its position based on new evidence.

Why do some drugs require a prescription while others can be sold OTC?

The manufacturer makes the initial decision as to which market to pursue. It submits data on the drug product to FDA, along with a recommendation for Rx or OTC status. The overwhelming criteria for whether a drug can be sold OTC relates to its effectiveness and safety for widespread use without physician supervision (Table 1). This also assumes that the patient can be accurately diagnosed without physician intervention.

The concepts can best be illustrated by example. Aspirin is safe and effective for short-term administration to treat minor pain such as headache, backache, and toothache. The drug is, therefore, available OTC.

TABLE 1

Criteria for a Drug Making it Safe and Effective for OTC Sale

An OTC drug is *SAFE* if it has a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability.*

An OTC drug is *EFFECTIVE* if there is a reasonable expectation that in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed.**

*CFR 330.10(A) (4) (i)
**CFR 330.10(A) (4) (ii)

Diflunisal (Dolobid®) and suprofen (Suprol®) are also safe analgesics when used as directed. But they are indicated for moderate to severe pain that requires a physician's diagnosis and his monitoring of therapy. Also, they have not been available long enough to determine whether they can be used without medical supervision. Therefore, they require a prescription for purchase.

Since doses of aspirin in excess of 650 mg are not considered safe for self-medication, products such as Easprin and ZORprin are available only on prescription, even though they contain only aspirin.

Another criterion is whether the condition is self-diagnosable and self-treatable, or whether it requires medical supervision. Over the years, three conditions/drug products have entered a "twilight zone". While peptic ulcer, diabetes, and bronchial asthma are not self-diagnosable, antacids, insulin, and epinephrine aerosols and certain theophylline-containing products are available OTC for treating these conditions.

Basically, the physician must first diagnose the condition and recommend treatment guidelines and doses. Then the patient is permitted to purchase the drug without a prescription, and in some instances, even decide which specific product he wishes to use.

There are other situations that are paradoxical. Consider the following.

Antivert/Bonine. Both products contain meclizine as their sole ingredient. Bonine® can be purchased OTC, while Antivert® requires a prescription. This is explained because the original Antivert® formulation contained meclizine plus niacin. The combination was indicated in the treatment of vertigo, Meniere's syndrome, and other malfunctions of the labyrinthine apparatus. When niacin was later shown by the DESI review to lack substantial effectiveness in these conditions, it was removed from the product. Since vertigo and Meniere's syndrome require physician diagnosis and supervision, and since Antivert® is still widely prescribed, its manufacturer has not initiated a switch in status.

TABLE 2
Potential Drug Shifts from Rx to OTC Status
Antianginals
Antimicrobial mouthwashes
H_2-antagonists
Skeletal muscle relaxants
Sucralfate
Urinary tract anti-infectives
Vaginal antifungals
Thiazide diuretics
Nonsteroidal anti-inflammatory agents

Bonine® is indicated solely for prevention and treatment of motion sickness, which is self-diagnosable and self-treatable. As long as its manufacturer makes no claims about vertigo or Meniere's syndrome, it may remain OTC.

Monistat/Mica-Tin. This antifungal agent is available on prescription as Monistat®, and OTC as Mica-Tin®. The products are identical, but FDA believes that ringworm is self-diagnosable/treatable and Candida infections are not. Since miconazole is effective against both types of organisms, it can be marketed OTC for ringworm. Claims that it is indicated for treating Candida infections give Monistat® prescription-only status.

Drugs Shifted from Rx-Only to OTC Status

Since the FDA/OTC review began, a number of drugs have changed from prescription to over-the-counter status. Table 2 lists classes of other drugs that have been suggested for future shifts.

Foremost among the drugs were the antihistamines. Chlorpheniramine's OTC dosage was raised from 2 mg to 4 mg, and the 8 mg and 12 mg sustained-release dosage forms were also shifted to OTC status.

Brompheniramine, dexbrompheniramine, dexchlorpheniramine, triprolidine, and diphenhydramine (up to 25 mg) were switched over as well. Again, the reason for the limit on diphenhydramine OTC strengths is that the indications for the 50 mg dose are not considered to be self-treatable.

There was also much activity with the nasal decongestants. The OTC dosage of pseudoephedrine was raised to 60 mg for regular release tablets and 120 mg for the sustained-release product. Phenylpropanolamine was increased to 37.5 mg for regular release tablets and 75 mg for sustained-action preparations. The topical decongestants, oxymetazoline and xylometazoline, were also made OTC products.

Other drugs recommended for a change in status from prescription to OTC during the FDA review include fluoride mouth rinses, hydrocortisone, the antifungals haloprogen and miconazole, the anthelmintic pyrantel pamoate, and antitussives benzonatate and chlorphedianol. Interestingly, the latter three items have not yet been marketed OTC.

Ibuprofen (up to 200 mg) has also shifted status. This was initiated by a recommendation from FDA's arthritis advisory committee, and the move was made by the new drug application process, rather than the OTC review procedure.

Third Class of Drugs

There has been considerable debate as to whether the U.S. should have a "third class" of drugs since one exists in nearly every other industrialized nation. This class would include drugs that do not require a prescription to purchase, but do require that the user take special precautions. The products would only be available in a pharmacy.

It could be argued that a third class of drugs is currently in existence in the U.S. Insulin is the only item in it. The sale of insulin is restricted to pharmacies because it is an injectable product, and by definition, a dangerous drug.

The concept that certain drugs should be available only from a pharmacist is intriguing and merits further discussion. The issue is controversial with strong supporters for both sides.

One position contends that sales of those drugs that are shifted from Rx to OTC status should be restricted to pharmacists only. Proponents claim that the potential for widespread abuse and toxicity of these drugs is great, and there should be a buffer zone (e.g., a third class) for them. This could be a temporary restriction lasting only until the general public learns to correctly use them, or until evidence can be accumulated to prove their safety without medical supervision. The argument is based on the premise that if pharmacists could assure that the items would be correctly used, abuse potential and toxicity would be limited.

Although others do not disagree with this concept theoretically, they have some reservations. The items that have been successfully switched to OTC status to date have not been abused or caused widespread toxicity. These items include hydrocortisone and ibuprofen which were anticipated to cause problems when available OTC. Opponents claim that other drugs being considered for the switch are equally safe. They also believe that FDA's procedures for switching drugs to OTC status are responsible.

Another argument is that there is no assurance that the third class would be sold with pharmacists counseling on their safe and proper use. Proponents believe, and unfortunately most studies have confirmed, that pharmacists as a group have failed in the past to take the initiative to counsel patients on OTC drugs unless specifically requested to do so.

Opponents also argue that a third class is monopolistic. They add that if self-treatment is a human right, the drug items should be available without restriction. Limiting sales to pharmacies would reduce access to them, especially for persons living in remote or rural areas.

They present a strong argument that the current two class system of drug distribution has worked well for America, that there are over 250,000 retail outlets for OTC drugs, that American consumers use OTC drugs responsibly, that most people do not need counseling, and that when they do ask their pharmacist, he or she does a good job. They continue that consumers should not be legislated into being required to visit a pharmacy to purchase otherwise safe and effective OTC products.

Other proponents state that such a limitation would reduce competition and thus increase prices. They further state that keeping certain drugs off retail shelves would prohibit consumers from making comparisons with other OTCs. They argue that the current labeling is, by law, clear and precise.

Are there benefits to the switching of Rx-only drugs to OTC?

The answer to this question is definitely "yes" from one perspective. The new OTC products represent a significant source of additional revenue to *pharmaceutical manufacturers*. Sales increases of 400 to 500 percent or more during the first year a drug is available OTC have already been noted.

One national sales audit revealed that the year before topical hydrocortisone became OTC, it accounted for $12 million in sales. During the first year after the switch, OTC sales totaled $70 million, with 75 percent of sales made in drug stores. Interestingly, prescription sales that same year increased 50 percent up to $18 million.

Consumers benefit because they have access to a wider variety of drug products. They save money because of fewer physician visits. An analysis of savings to the consumer (financed by the Proprietary Association) estimated that during the first three years of OTC availability of hydrocortisone products, the American public saved more than $1 billion, in not having lost time waiting for a physician, the cost of the physician visits, and prescription expenses.

Pharmacists may benefit, or lose, the most depending on how they handle the situation (opportunity!). Each new OTC item offers pharmacists an expanded role for assuring that patients understand how to properly use the products. In doing so, it helps the patient and also helps the pharmacist's self-esteem.

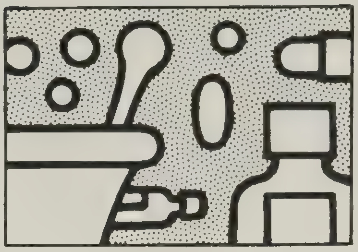
On the other hand, if pharmacists idly stand by and refuse to accept the challenge of being the drug experts that they really are, they will lose all of the sales volume they formerly had when the items were restricted to prescription, and could lose most of the sales as OTCs.

Overview

The switching of certain Rx drugs to OTC status represents one of the most significant developments in the OTC marketplace in many years. The economic impact is massive and will affect nearly all segments of health care. The challenge is there. Enterprising pharmacists will accept the challenge and turn it into an opportunity.

Clip and Reproduce

Things You Should Know FOR YOUR GOOD HEALTH



Flu Season Is Here Again — Use Sensible Precautions

Coughs, sneezes, chills and fever; they are just around the corner. During the winter months we all become more susceptible to common colds and influenza (commonly known as the flu). Influenza is a respiratory disease caused by two types of influenza viruses, A and B. Each type includes many related strains. Examples of the various strains are: type A/Bangkok or type B/Singapore (named after the place where the virus first appeared.)

Following exposure to the virus, symptoms will develop rapidly, usually within one to three days. Some of the initial symptoms which may appear are chills, headache, muscular aches, weakness and backache. All or just a few of these symptoms can be present. Most people will lose their appetite within the first day. Fever often accompanies the flu. Body temperature may increase rapidly to 101 or 102 degrees Fahrenheit during the first day of symptoms. It usually peaks at 103 degrees Fahrenheit or less. Generally the fever goes down gradually over a few days; however, in some cases it may drop quickly only to rise on the third day. Usually it lasts about three to four days, but it may last for as long as a week.

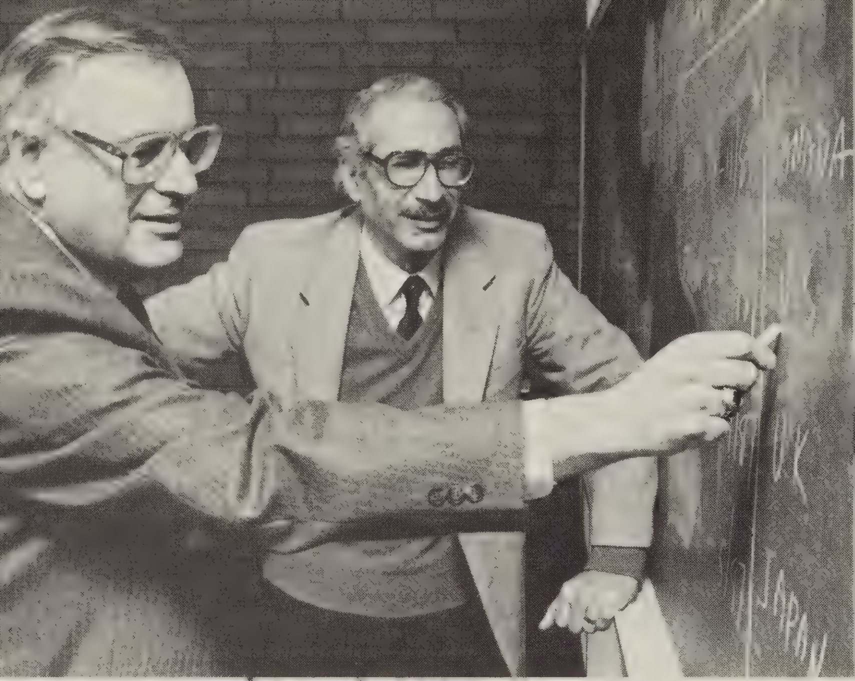
As the temperature drops, stuffiness and a cough may develop. Once this stage is reached, recovery is on the way. However, weakness may last for one to three weeks longer. People in very poor health may take even longer to get strength back following a bout with the flu. A loose cough may linger for a few weeks. It is highly recommended to stay at home for at least two days after the fever has gone down. Since influenza lowers one's resistance to other illnesses, exposure should be avoided until full recovery has occurred.

Another type of disease which occurs during the winter months is known as intestinal or stomach flu. This illness is caused by a virus too, but not one of the influenza viruses. The common symptoms of stomach flu include diarrhea, stomach cramps or vomiting.

When family members, friends and co-workers become sick with influenza, the air is full of viruses and it is nearly impossible to avoid getting in the path of a few coughs and sneezes. However, there are a few precautions which can be taken. Keep up resistance by getting plenty of rest and eating regular, well-balanced meals. For the short duration of an influenza outbreak, stay out of crowds as much as possible and wash hands frequently and thoroughly with warm, soapy water. If a family member has influenza, keep his or her dishes and towels separate from the rest of the family's. The sick person should cover his coughs and sneezes with paper tissues and drop them at once into a trash bag. Dispose of the trash frequently.

Most physicians recommend bed rest for the treatment of influenza. Aspirin or acetaminophen helps ease the pain and bring down the fever. Drink plenty of fluids especially in the presence of a high fever. Antibiotics are not effective against viruses. Physicians may prescribe an antibiotic, however, if a bacterial infection develops as a result of the flu. Remember, do not take prescription medications unless prescribed especially for you by your physician. For advice about over-the-counter (non-prescription) medication, ASK YOUR PHARMACIST.

© SPEA



SYNTEX. PHARMACISTS AT WORK.

These professional pharmacists are typical of the scores of pharmacists at Syntex who are responsible for all types of important functions—from research to sales.

In fact, our highest ranking pharmacist is President and Chief Operating Officer of the Syntex Corporation. He's Paul E. Freiman, R.Ph., and he's responsible for just about everything we do. He brings the viewpoint of a trained pharmacist to the very highest corporate level.

Pharmacists also fill many other key positions at Syntex. They help keep us in touch with the real world of pharmacy, and we think that benefits everyone.

Pharmacy for pharmacists by pharmacists. That's Syntex.

SYNTEX

SYNTEX LABORATORIES, INC
PALO ALTO, CA 94304

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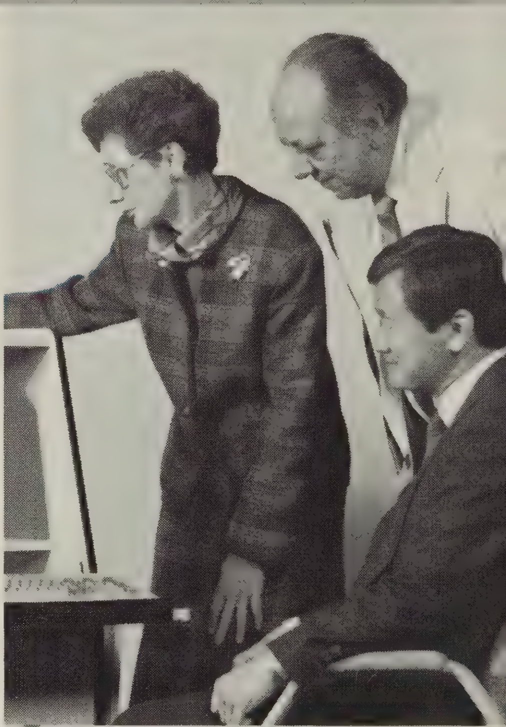
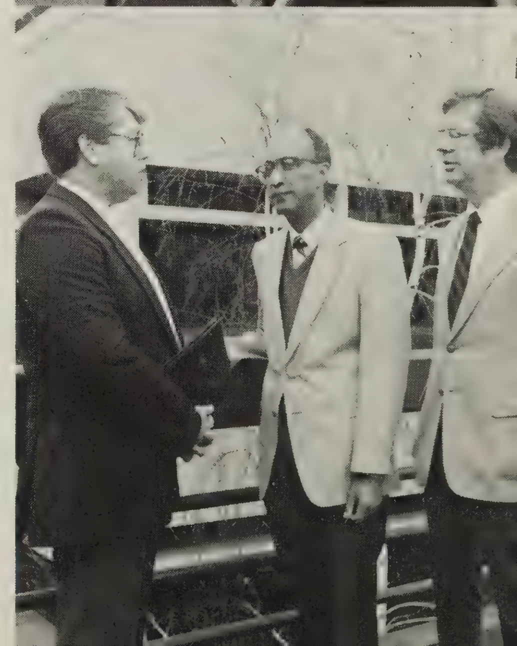
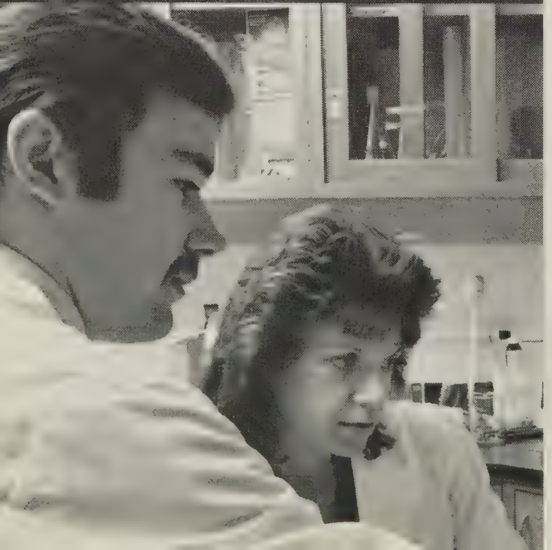
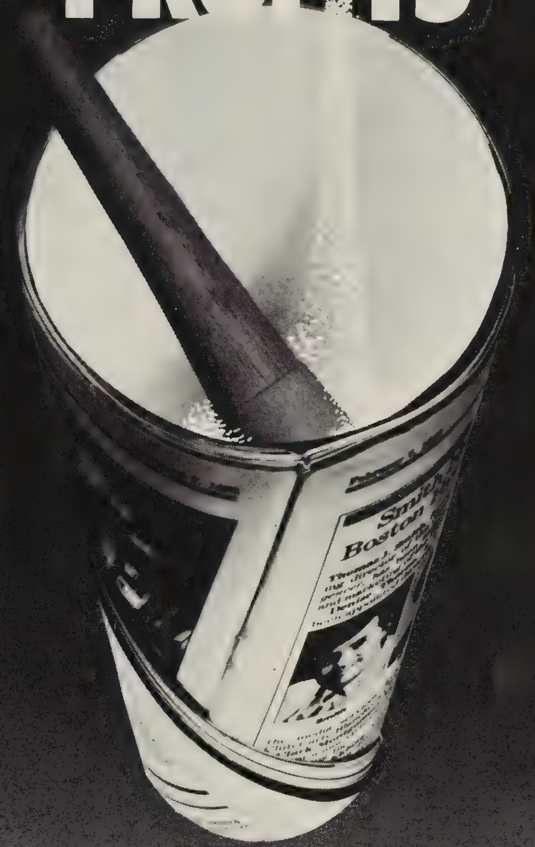






PERIODICALS
COMPOUND
YOUR
PROFITS



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Established 1923 Magazines/Books/Newspapers

Continuing Column

The Pharmacist and Hospice

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**IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?**

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

MANAGEMENT OF NAUSEA AND VOMITING

Nausea and vomiting as stated in the last newsletter remains a common concern for patients who are seen in a hospice program. In an effort to limit the patient's discomfort and debilitation due to the toxicities of chemotherapy, a variety of antiemetic trials have been conducted. Included among the agents that have been used to decrease nausea and vomiting associated with cancer chemotherapy are the cannabinoids.

Clinical trials with cannabinoids were encouraged by anecdotal reports of decreased emesis in younger patients who used marijuana when receiving their chemotherapy. The majority of trials in recent years have been conducted with tetrahydrocannibinol (delta-9-THC), although two synehetic cannabinoids, nabilone and levonantradol, have also been tested in several clinical studies. The mechanism of action of the cannabinoids as an antiemetic remains unclear.

Antiemetic results have been conflicting among different studies. Despite this, THC has generally been found to be superior to placebo and equivalent or superior to oral prochlorperazine (Compazine) therapy. In addition to its antiemetic properties, one study found that some patients actually had an increase in their appetites while using THC. This may be clinically important to patients who suffer from chemotherapy or radiotherapy-induced anorexia.

THC appears to be more effective against chemotherapeutic agents of lower emetogenic potential. In one study that compared THC to high-dose IV metoclopramide, the latter drug showed superior results although both agents were effective and generally well-tolerated by the patients. The study centered around nausea and vomiting induced by cisplatin, an extremely active emetic drug.

In a study comparing levonantradol with THC, results showed equivalent antiemetic efficacy and toxicity. Levonantradol is currently under review by Pfizer Central Research for commercial availability. Since levonantradol has been used both parenterally and orally, its prospective availability may offer itself as a useful addition to the cannabinoid antiemetic agents, since a parenteral agent may be preferable once vomiting has begun.

DRUG FOCUS: Dronabinol (Marinol®)

Dronabinol is the generic name for THC which is the active ingredient in marijuana. It has recently been approved for treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatment.

The drug has varied and complex CNS effects. Patients can experience mood changes including euphoria (24%), detachment (11%), depression (7%), anxiety (16%) and panic or paranoia (2%). Drowsiness occurs in about 50% of the patients, while dizziness is a problem in about 20%. A decrease in cognitive function and memory (9–12%) can also occur, especially with larger doses of the drug.

There have been inconsistent effects on blood pressure with some subjects experiencing orthostatic hypotension and tachycardia (1%). This is most likely due to a general increase in central symspathomimetic activity. Because of dronabinol's potential to alter the mental state, the drug should always be administered to patients who are under the supervision of a responsible individual.

Dronabinol is 10–20% bioavailable and undergoes extensive first-pass metabolism. The maximum plasma concentration of dronabinol and 11-hydroxy-THC, an active metabolite, occurs 2–3 hours after oral dosing. Biliary excretion is the major route of elimination with 50% of the dose recovered in the feces within 72 hours. The elimination of the drug is biphasic and therefore extended use may yield accumulation and toxicity.

Dosing regimens may vary, but the manufacturer recommends that initial doses are 5 mg/m^2 2–4 hours prior to treatment, then every 2–4 hours during treatment for a period of 24 hours. An average daily prescription for a therapeutic regimen might require six capsules of the desired strength. The dose can be increased in increments of 2.5 mg/m^2 to a maximum of 15 mg/m^2 per dose if necessary. The capsules should be stored in a *cool* place for optimum stability.

Dronabinol, although manufactured by Unimed, will be available sometime in July of 1986 through Roxanne Labs. It is classified as a Schedule II drug and will be available as a liquid capsule (dissolved in sesame oil in soft gelatin capsules) in 2.5 mg, 5 mg and 10 mg strengths.

U.S.P. LEAFLET◆ DISKETTE

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See page 16

"RETURN GOODS POLICY MANUAL"

New third edition contains the return goods policies of over 150 pharmaceutical manufacturers in a standard format. The policies are in a three ring binder to allow for updates and additions.

The ***RETURN GOODS POLICY MANUAL*** provides information on:

*who to contact if a sales representative is not available

*company addresses and phone numbers

*what items are and are not returnable

*the procedure for returning items

*the type of compensation to the pharmacy, i.e. credit or exchange

*transportation charges

*company disclaimers

**and much more.

Please allow 4 to 6 weeks for delivery.

Please send me _____ copy(ies) of the ***RETURN GOODS POLICY MANUAL*** at $30.00 each (includes postage and handling).

_____ check enclosed

____ VISA ____ Mastercard

#_______________________________

Exp. Date_______________________________

Name _______________________________

Address _______________________________

____

Mail to:

Maryland Pharmaceutical Association
650 W. Lombard Street
Baltimore, Maryland 21201

Announcing

The Independent Pharmacy Matching Service

NARD, in response to member requests, has established an exciting new member program called the Independent Pharmacy Matching Service (IPMS). IPMS is a national network for independent pharmacists who are seeking new employees or jobs for themselves, and it matches pharmacists who wish to buy or sell a pharmacy. The IPMS program will be launched at the 89th Annual NARD Convention in Las Vegas, NV, October 18-22, 1987.

How does it work? If you want to sell your pharmacy, buy a pharmacy, or locate and hire a new pharmacist or manager, complete an IPMS participation form and send it to NARD. Through an NARD-designed computer program, potential buyers are matched to pharmacy sellers and potential employees are matched to pharmacists looking for employment. If a match is found, both participants are informed of the mutually beneficial opportunity.

For example, let's say you want to sell your pharmacy. You complete the IPMS participation form and send it to NARD. When NARD receives an IPMS participation form from a potential buyer who is looking for a pharmacy in your geographical area, or with your sales volume, daily prescription activity, or other criteria, the buyer is given your name and phone number. No other pharmacy information is released. NARD also contacts you with the name and phone number of the interested buyer. After that, it's up to you and the buyer to set up a time to meet and close the deal.

What does it cost? At this first annual convention, the IPMS service is *free* for registrants who complete and return the annual registration form. Subsequently, the cost is only $25 per participation form. Please note that in order to participate, *you must be an NARD member.*

For further information on this exciting new program for independent retail pharmacists, contact NARD's Department of Professional Affairs toll free at 800-544-7447 between 1:00 and 5:00 p.m. Eastern time.

Independent Pharmacy Matching Service Participation Form

Please type or print legibly all requested information. NARD holds all IPMS submissions in strictest confidence.

PARTICIPANT INFORMATION

Name: ____________________

Pharmacy: ____________________

Mailing Address: ____________________

City/State/Zip: ____________________

Pharmacy Phone Number: ____________________

Home or Alternate Phone Number: ____________________

NARD Member Number: ____________________

I am seeking (check one only per form)
( ) to sell a pharmacy *(complete section one)*
( ) to buy a pharmacy *(complete section two)*
( ) to hire a new pharmacist/manager *(complete section three)*
( ) to obtain a new position *(complete section four)*

SECTION ONE: PHARMACY PRACTICE FOR SALE

Annual Sales Volume ________ Daily Rx Volume ________

Current Value of Inventory _____ Years in Business _____

Own or Lease Building _________ Selling Price _________

Please attach a 25-word description of your pharmacy.

SECTION TWO: LOOKING TO BUY A PHARMACY PRACTICE

Please attach a 25-word description of the pharmacy you wish to buy.

SECTION THREE: LOOKING TO HIRE A NEW PHARMACIST/MANAGER

Position ____________________

Starting Salary __________ Benefits __________

Years of Experience Required ____________________

Please attach a 25-word description of the position and the ideal candidate's qualifications.

SECTION FOUR: LOOKING TO FIND A NEW POSITION IN INDEPENDENT RETAIL PRACTICE

Type of Position Sought ____________________

No. Years of Experience _________ In Retail _________

Year of Graduation ____________________

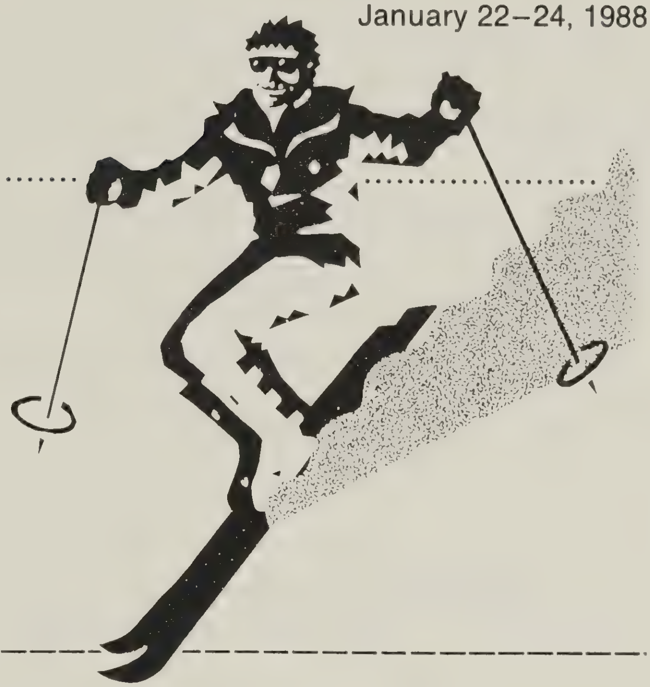
Please attach a 25-word description of yourself and your career objectives.

RETURN TO: DEPARTMENT OF PROFESSIONAL AFFAIRS
NARD
205 DAINGERFIELD ROAD
ALEXANDRIA, VA 22314

SKI WEEKEND GETAWAY

U of M School of Pharmacy Alumni
MD Pharmacists Association

January 22–24, 1988



SKI GREEK PEAK
LODGING AT THE RAMADA INN,
Binghamton, NY

LOOK WHAT'S INCLUDED!

ROUNDTRIP TRANSPORTATION:
via lavatory equipped motorcoach.

2 NIGHTS ACCOMMODATIONS AT THE RAMADA INN BINGHAMTON:

- ▶Deluxe, comfortable rooms featuring color TV and individual climate control.
- ▶Indoor pool and Scandinavian saunas.
- ▶3 great night spots on the premises:
  - —ESPRIT CLUB: Dance the night away at Binghamton's largest and most popular dance club where you will be mesmerized by the spectacular light and sound show.
  - —IMAGES: This fireside adult entertainment lounge is the perfect place to listen to your favorite music, enjoy billiards, darts, old-time movies, shuffle board, video games, fresh popcorn, deli sandwiches and your favorite drinks.
  - —JENNIFERS LOUNGE: A cozy night spot featuring big screen entertainment.

4 SCRUMPTIOUS BUFFETS:

- ▶2 hearty "all you can eat" breakfasts
- ▶2 delicious dinners: four course sit down dinner on Saturday featuring your choice of "King Cut" Prime Rib or Boneless Breast of Chicken and an International Steamship buffet on Sunday.
- ▶Saturday Evening Dining Option . . . Exchange your buffet coupon for a credit towards dinner in Jennifer's restaurant choosing from the regular menu.

DANCING, PARTIES AND NONSTOP FUN!!

- ▶Welcome reception upon arrival with refreshments.
- ▶2 Aprés Ski Parties on Saturday and Sunday afternoons feature 99¢ drink prices, hot and cold hor d'oeuvres with free wine on Sunday.
- ▶Unbeatable nightlife alternatives in Esprit, Images and Jennifers.
- ▶Midnight horror film on Saturday night in Jennifers.

SKIER SERVICES:

- ▶Unlimited free ski lessons at Greek Peak each day with the purchase of a lift ticket.
- ▶Daily transfers to Greek Peak / Availability of a Tours de Sport Ski Rental Shop in the hotel.

ALSO INCLUDED:

- ▶Transfers provided on Sunday to shopping, ice-skating* and roller-skating,* horseback riding,* and horse drawn sleigh rides.*
- ▶Services of Tours de Sport's on-site staff / Tour Guide on bus / Itinerary / Late checkout / Taxes & gratuities.

FOR MORE INFORMATION CONTACT:
Brian T. Sanderoff: 752-3473 D
Beverly Litsinger: 727-0746 D

PRICES PER PERSON:
4 in a room—$124.00
3 in a room—$139.00
2 in a room—$154.00

MAKE CHECKS PAYABLE TO:
Maryland Pharmacists Association

PAYMENT SCHEDULE:
$35.00 due by 11/05/87
Final balance due by 12/25/87

BUS DEPARTURE SCHEDULE:
The bus will depart at 6:00 PM on Friday January 22, 1988 from Security Square Shopping Center, Security Blvd.

POSSIBLE C.E. PROGRAM AVAILABLE—ASK BRIAN!

NOT INCLUDED IN TOUR PRICE:

- ▶Discount lift tickets** sold right in hotel.
- ▶Ski Rentals** (skis, boots & poles) for the entire weekend . . . only $15 per person.

*** Payment for these options will be collected at the hotel (CASH ONLY PLEASE).*

TOURS DE SPORT

SKI GREEK PEAK
CENTRAL NEW YORK'S LARGEST SKI RESORT
23 slopes and trails from beginner to expert / 900′ vertical rise / 8 lifts / Longest trail 1.5 miles / 27 miles of cross country trails / 85% snowmaking / Certified ski school and ski patrol / Base lodge with restaurant, bar and ski shop.

PHARMACY ACHIEVEMENT SCHOLARSHIP UNIVERSITY OF MARYLAND

School of Pharmacy

The University of Maryland School of Pharmacy's Annual Pharmacy Achievement Scholarship represents an exciting challenge to you as a practitioner concerned with the future of our profession. By sponsoring a qualified high school or college student (Maryland Resident) for this tuition-free one-year scholarship, you will:

1) stimulate general community interest in the profession;
2) encourage one outstanding young person of your acquaintance to choose pharmacy as a career;
3) demonstrate to your colleagues an awareness of the need for more and better pharmacy students.

The guidelines are simple. The student that your sponsor must have a satisfactory record of achievement in high school or college, an interest in pharmacy as a career, a cumulative grade point average of 2.75 or equivalent, and PSAT/SAT scores ready for submission. He or she then completes the Student Section of the form enclosed, while you complete the Pharmacist's Section. *You* then *mail both forms*—to be received no later than midnight December 15th—to:

The Pharmacy Achievement Scholarship Committee
University of Maryland—School of Pharmacy
20 North Pine Street
Baltimore, Maryland 21201

That's all there is to it.

The recipient will be selected by representaives of the School of Pharmacy, the Maryland Pharmaceutical Association, the Alumni Association, the Maryland Pharmaceutical Society and the Maryland Society of Hospital Pharmacists. The award (one year's tuition) will be announced at a formal ceremony for all nominees and sponsors at the School of Pharmacy during the Spring term. The recipient will be required to meet established admission requirements for the School of Pharmacy at the time of entry.

For additional forms or further information, call Dr. Grady Dale, Director of Student Affairs, 328-7650/328-6586.

UNIVERSITY OF MARYLAND PHARMACY ACHIEVEMENT SCHOLARSHIP

APPLICATION
(Please type or print)

PHARMACIST'S SECTION

I nominate ____________________ for the School of Pharmacy Annual Pharmacy Achivement Scholarship.

Pharmacist's Name: ____________________

Address: ____________________

Name of Pharmacy: ____________________

College of Pharmacy: __________ Degree ____

Year ____________________

Telephone # ____________________

Indicate below why you feel this student is deserving of this scholarship. Include how you came to know the student and his/her qualities and attributes. Also include your knowledge of his/her extracurricular activities and how the student has demonstrated an interest in pharmacy as a career.

**Note: All writing must be kept within the space provided. No additional information may be attached. To do so may void the application.

Please make sure the student you have nominated has completed all the information on the other side of this application before sending to the Scholarship Committee.

____
Sponsoring Pharmacist's Signature

____
Date

Send completed form to:
Pharmacy Achievement Scholarship Committee
University of Maryland-School of Pharmacy
Baltimore, Maryland 21201

STUDENT SECTION

Date of Application ____________________

Name: ______________________________ Telephone # ____________________

Address: ____

Permanent Address (if different from above) ____________________

List your most recent place(s) of employment (if any):

Employer	Dates of Employment	Brief Description of Duties
1.		
2.		

Indicate any extracurricular (social or service) activities.**

Briefly, how did you become interested in pharmacy as a career?**

Describe how you came to know the pharmacist nominating you for this scholarship.**

Include transcript of high school grades (college transcript if beyond first year of college). PSAT, SAT and/or ACT scores must be submitted if not included on transcript. NOTE: The awarding of the scholarship does not constitute admission to the School of Pharmacy. The recipient must be a bona full-time student at the University of Maryland School of Pharmacy in order for the scholarship to be activated.

____

Student's Signature

Note: DO NOT WRITE OUTSIDE of the box or attach additional information. To do so may void the application. THIS APPLICATION MUST BE RECEIVED NO LATER THAN DECEMBER 15TH.

Dear Dave:

APhA was as surprised as you and some of your members to see the Giant Discount drug advertisement carrying the APhA "endorsement." The advertisement was not reviewed in advance by APhA, as you probably surmised from the fact that it carried the old-style APhA logo rather than the new one. We had started investigating the matter when you expressed concern to us during the ASPAE meeting. As I know you can appreciate, it has taken time to gather the facts and subject the matter to both legal and policy review.

Giant's "Profile" system utilizes the Medicom Drug Interaction Data Base, which is the *Evaluations of Drug Interactions* (*EDI*) data base in electronic media form. *EDI* was originally developed and published by APhA in 1973, with a second edition in 1976 and a supplement to the second edition in 1978. In 1982, APhA entered into an agreement with Professional Drug Systems, Inc. (PDS), which included publication of *EDI* by the C. V. Mosby Company and marketing of the computerized database as PDS' Medicom Drug Information Package. The agreement permits indication of APhA endorsement since both published and computerized versions are subject to approval by an *EDI* Review Panel appointed by APhA. The computerized version, Medicom, has subsequently been marketed by PDS to both independent and chain community pharmacies.

Nevertheless, we do have concerns about the Giant advertisement since the language used could be interpreted to mean that APhA endorses Giant's "Profile" system. This, of course, is not the case; the Association endorsement applies only to the drug interaction data base utilized in the "Profile" system.

Those pharmacists who might have misinterpreted the advertisement and thus thought that APhA had endorsed a patient medication profile system used by Giant to the exclusion of all other systems understandably would be upset. The APhA endorsement of the Medicom Drug Information Package merely helps to assure the quality and accuracy of information that is available to *any* purchaser of that information. Thus any purchaser's appropriate reference to APhA's endorsement would be acceptable in the same way that an advertisement noting that a company's pharmacists use the APhA *Handbook of Nonprescription Drugs* in counseling patients would be acceptable. We are now holding discussions with Giant officials to seek clarification of the manner in which APhA's name may be used in the situation.

While we understand that many pharmacists find some of Giant's business practices objectionable, these practices are totally unrelated to Giant's use of the Medicom Drug Information Package, a quality product that is available to all pharmacists.

It is important that all pharmacists understand the facts concerning Giant's reference to APhA, and therefore we would appreciate your bringing this letter to the attention of your members. We would be very happy to have a member of our staff discuss the matter at an MPhA meeting or meeting of your leadership.

Do not hesitate to contact me if you wish to discuss this further.

Sincerely,
John F. Schlegel, Pharm.D.
President

American Pharmaceutical Association

USP LEAFLETS NOW AVAILABLE ON COMPUTER DISKETTE

The text for the 80 USP Patient Education Leaflets currently available in preprinted form is now accessible for computer use. The USP Leaflet Diskette contains all programming and leaflet text on a single 5¼-inch, 360K floppy disk. It is a stand-alone program, which will run on an IBM PC, XT, AT, or compatible computer with 256K of memory and 360K floppy disk drive(s). Each diskette comes with full documentation, instructions, and a printed index of drugs (both brand and generic names). The 80 titles cover over 2000 products.

Leaflets can be printed on demand with a standard line printer. Therefore, a leaflet program can be instituted without inventory or storage problems. Users need enter only the first letter of the drug (brand or generic) to be directed to the appropriate index section. After the specific product name is selected, the press of another key will automatically identify the proper leaflet text for printing. The drug name selected, whether brand or generic, will be the one printed on the leaflet itself.

Five lines at the top of each leaflet can be programmed to allow for a personalized message (e.g., pharmacy name, address, telephone number). In addition, the capability exists for adding the name of the patient, the prescription number, and patient-specific dosing instructions.

Each diskette is $229.00 for a one-year licensing agreement that provides unlimited use in a single computer. Multiple diskettes for multiple-site use are available at a quantity discount. Agreements are renewable annually and updated diskettes will be issued when new text is published.

To order the USP Leaflet Diskette, contact the USP Order Processing Department at 1-800/227-USPC.

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Resources for the Patient

Public Health Service AIDS Hotline
(800) 342-2437
National AIDS Testing
(800) 356-2437
National AIDS Prevention
(800) 872-8378
AIDS Hotline & AIDS Help
(800) 634-7477
Pediatric AIDS Hotline Albert Einstein College of Medicine
(212) 430-3333
Hemophilia Foundation in New York City
(212) 682-5510
Haitian Coalition on AIDS
(718) 855-0972
New York City Department of Health AIDS Physician's Hotline
(212) 340-4432
Lenox Hill Hospital AIDS tape
(212) 794-2200
National Gay/Lesbian Crisisline
(212) 529-1604
New York City Runaway Youth Hotline
(212) 619-6884
PWA (People with AIDS) Coalition of New York
(212) 242-3900
Saint Clare's Hospital and Health Center
(800) 433-2437
Mid-Hudson Valley AIDS Task Force
(914) 993-0607
Gay Men's Health Crisis New York City
(212) 807-6655
IV Substance Abuse-AIDS Hotline Beth-Israel Medical Center New York City
(212) 420-4141
New York City AIDS Hotline
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Gay Switchboard
(212) 777-1800
Health Resources Administration AIDS Helpline
(212) 645-7070
National Hemophilia Foundation Metropolitan Chapter
(212) 682-5510
New York City Victim Services Agency Hotline
(212) 577-7777
AIDS Resource Center
(212) 206-1414
Samaritans
(212) 673-3000
AIDS Council of Northeastern New York
(518) 445-AIDS
AIDS Rochester, Inc.
(716) 232-4430
Southern Tier AIDS Program
(607) 723-6520
Long Island Association for AIDS Care, Inc.
(516) 385-AIDS
New Jersey Department of Health AIDS Office
(800) 624-2377 (within New Jersey)
(800) 367-6543 (outside New Jersey)
National AIDS Hotline Sponsored by CDC
(800) 342-AIDS
San Francisco AIDS Activity Project
(415) 863-AIDS
Shanti Project of San Francisco
(415) 558-9644
Haight, Ashbury Free Medical Clinic IV Drug Users Program of San Francisco
(415) 621-2014
San Diego AIDS Project Hotline
(619) 260-1304
Hyacinth Foundations of New Jersey
(201) 264-8439
Aids Coordinator Hartford, CN
(203) 566-5058
Fenway Community Health Center of Boston
(617) 267-7573
AIDS Action Project of Howard Brown Memorial Clinic in Chicago
(800) 243-2437
Central New York AIDS Task Force
(315) 475-AIDS
Western New York AIDS Program
(716) 847-AIDS
New Jersey AIDS Hotline
(201) 596-0767
AID-AIDS in Chicago
(800) AID-AIDS
AIDS
(800) 376-AIDS (Northern California)
(800) 922-AIDS (Southern California)
San Francisco AIDS Foundation
(800) FOR-AIDS
Operation Concern AIDS Worried Well Group of San Francisco
(415) 626-7000
San Francisco AIDS Foundation, Women's AIDS Network
(415) 864-4376
AIDS Project of the East Bay Pacific Center for Human Growth
(415) 420-8181
AID Atlanta of Atlanta, GA
(404) 872-0600
Health Crisis Network in Miami, FL
(305) 634-4780
Cares Team of Los Angeles
(213) 464-2273
D.C. AIDS Task Force Whitman Walker Clinic of Washington, DC
(202) 332-5295
(202) 332-AIDS
Philadelphia AIDS Task Force
(215) 232-8055
Baltimore Health Organization Resource Organization (HERO)
(301) 945-AIDS
AIDS Action Council of Federated AIDS-Related Organizations in Washington, DC
(202) 483-7979
AIDS Project of Portland, ME
(800) 851-AIDS
(207) 775-1267
AIDS Center One of Fort Lauderdale, FL
(800) 325-5371
National Association of People with AIDS (NAPWA) of Washington, DC
(202) 483-7979
AIDS Hotline of the AIDS Project of Los Angeles
(213) 871-AIDS
AIDS in Florida
(800) 352-AIDS (within Florida)

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Through their experience as pharmacists, we explored your concerns.

Through their insights as panelists, we discovered new ideas.

The members of our 1987 Pharmacy Consultant Panel spoke from personal experience. But their ideas and concerns spanned the breadth of our profession. We thank them for sharing their wisdom, experience and advice. Most of all, we look forward to putting their ideas to work to serve pharmacy professionals better.

Standing Left to Right:

Jack R. Cole, Pharmacist
Dean, College of Pharmacy
University of Arizona
Tucson, AZ

Reed Rosling, Pharmacist
Vice President, Hospital Sales
Bergen Brunswig Drug Company
Orange, CA

Thomas M. Ryan, Pharmacist
Vice President, Pharmacy Operations
Consumer Value Stores
Woonsocket, RI

William G. Thien, Pharmacist
Vice President
Health Services & Pharmacy Operations
Walgreen Drug Stores
Deerfield, IL

Darwyn J. Williams, Pharmacist
President
Williams Drugs Inc.
Webster City, IA

Seated Left to Right:

John H. Vandel, Pharmacist
President
Vandel Drugs, Inc.
Torrington, WY

Marily Rhudy, Pharmacist
President
Continental Pharmacy, P.A.
Topeka, KS

Thomas R. Temple, Pharmacist
Executive Director
Iowa Pharmacists Association
Des Moines, IA

M. Patricia Lee, Pharmacist
Director of Pharmacy
UCSD Medical Center
San Diego, CA

Upjohn

Not pictured: Bernard Mehl, Pharmacist, Director of Pharmacy Mount Sinai Hospital, New York, NY
John J. Piecoro, Jr., Pharmacist, Associate Director Clinical Services Chandler Medical Center, Lexington, KY

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Mandatory Counseling???

by Jim Dickinson

Mandatory counseling. Should pharmacists be required by law to counsel their patients? Possibly as a response to the challenge of mail-order operators and physician-dispensers, this question is being debated in a growing number of state legislatures.

For some pharmacists, like the middle-aged owner who questioned me at the Indiana Pharmacists Association meeting September 12, counseling is a double-edged sword—yes, mail-order firms can't do it, but what about our liability?

Coached by years of foreword-thinking pharmacist-attorneys like West Virginia University's David B. Brushwood and USP's Joseph G. Valentino, I told the questioner that the risk is so infinitesimal it's well worth grabbing with both hands.

A little-known fact is that no pharmacist has even been penalized by a court for giving wrong advice; to the contrary, they are starting to be found guilty of *not* giving advice.

Self-serving lawyers who would advise pharmacists, and keep them nervous so that they will need more and more advice, have obscured that statistic.

They have also obscured another obvious point (nothing's obvious, however, when a skilled lawyer is busy frightening you): Even if a pharmacist is sued for giving wrong advice, it almost inevitably will boil down to one person's unsubstantiated word against another's, or in legal language, to "hearsay evidence."

The tide in favor of counseling is beginning to surge. I was even advised at the Indiana meeting by a pharmacy owner so that his local Druggists' Mutual rep has been arguing that counseling will bring down pharmacists' insurance premiums.

But counseling isn't a clear-cut issue.

If a state law, explicitly written and enforced, requires counseling, then a great deal may be made by lawyers of professional "standards" that address counseling.

Frank Duckworth, a 1942 University of Florida pharmacy graduate who rose to corporate counsel status in Pfizer before becoming full-time president of the Food and Drug Law Institute last year, is among those legal scholars who worry about pharmacy's penchant for declaring professional goals to be "standards."

For example, in 1979, then-assistant executive director of the American Association of Colleges of Pharmacy John F. Schlegel (now president of the American Pharmaceutical Association) and APhA director of education Samuel H. Kalman proclaimed "Standards of Practice or the Profession of Pharmacy" based on five years of observation of what pharmacists (even one or two) do (or say they do) every day.

All of these are desirable goals for every pharmacist to aspire to, but Duckworth sees them with the lawyer's eye as potentially enforceable *legal* standards in the hands of a jury.

Giving the Fourth Annual Albert F. Wojcik Pharmacy Law Lecture at West Virginia University in September, Duckworth said:

"Some (standards) include statement of practice that are not generally accepted but rather are statement about what they hope will exist at some point in time. For instance, one set of these so-called 'standards' (Schlegel-Kalman) states that, in carrying out his duties the pharmacist 'assesses the patient's level of anxiety regarding the prescription/disease'—and 'explains to patient how to recognize the signs and/or symptoms that occur'—and 'advises patient how to minimize side effects'—and 'assesses whether patient understands explanation.'

"All of this is done," Duckworth commented, "after the pharmacist has interrogated the patient about any predisposition to side effects, as well as 'signs and/or symptoms of potential problems,' has determined alternatives to 'present regimen,' and has ascertained the patient's 'life style,' compliance history, attitude toward disease and medication, physical and medical impairments, 'socioeconomic restraints,' and living conditions.

"Then the pharmacist is to determine what he believes the appropriate dosage regimen should be, consulting with the physician 'when necessary.'

"Do you believe that retail pharmacists now have, or should have, a legal duty to do these things? If they do, they are in a heap of trouble."

The "trouble" that Duckworth sees is that when such desirable goals to aspire to are labeled "standards

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This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

of practice," or "codes, or even "guidelines," such labels create legal duties.

Now Duckworth admits he is of the old school, and he spoke at WVU with a certain nostalgia for the days when pharmacists only had to worry about how accurately they filled the prescription, leaving all other concerns to the physician.

He acknowledges that times have changed, and that pharmacists pursuing the new goals have a great deal to offer patients and physicians, both of which groups have also had change thrust upon them for good as well as for bad.

But he makes a narrow, limited point that is very valid, and that should not be taken by pharmacists as a caution against counseling.

That point is: "Don't call these new roles and functions "standards" or "codes" or "guidelines," because lawyers also use those terms, in once in a blue moon they may try to make trouble for you (as already noted, counseling only boils down to one man's word against another, so the trouble won't be as awful as Duckworth fears).

I asked Brushwood about all this, and he agrees that a better word would be "goals." To *aspire* to.

And the dreadful legal consequences of counseling should be put in perspective, too, he says. For example, in the most famous new pharmacy liability case, *Riff v. Morgan,* where the pharmacist was held 65% liable for a failure to counsel at all, Brushwood thinks the judgment might have been softer if, instead of saying "There is no duty to warn," the pharmacist had said, "There is a duty and I observe it always, but in this case I did it differently."

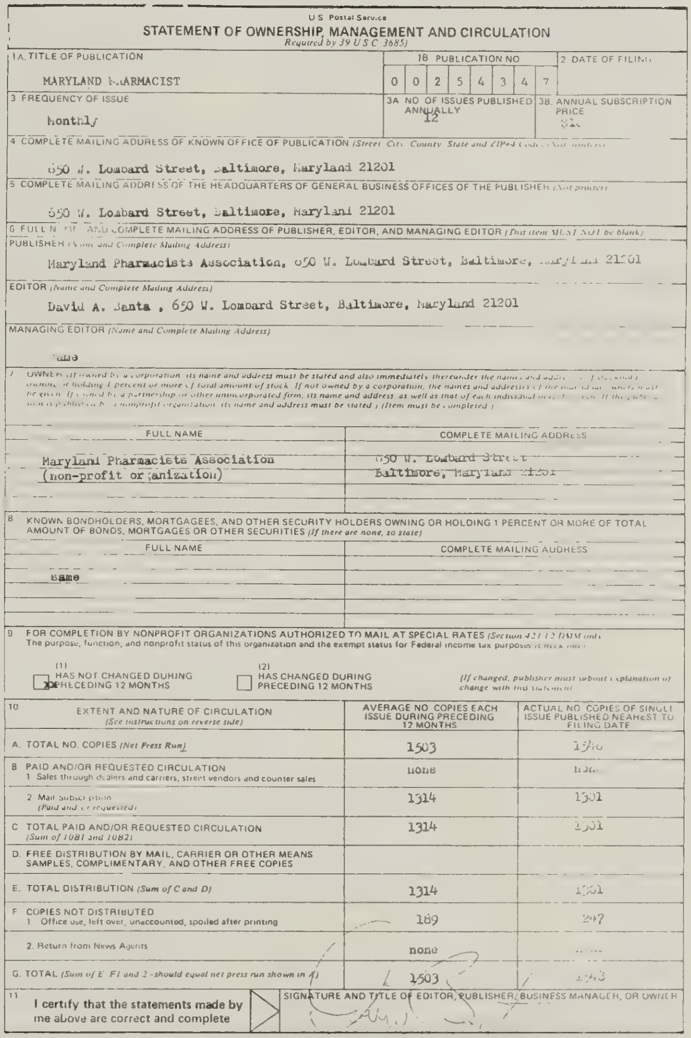
That, Brushwood thinks, could have given the pharmacist the opening to place blame elsewhere and to explain how the pharmacist's duty can sometimes be met, in special circumstances, by not doing the obvious.

Brushwood's point has appeal. Almost invariably, the pharmacist pleads to the court, "I'm only a seller, and I have no other duties." Increasingly, as *Riff* makes clear, courts will not accept that.

And neither should anyone else.

A·T·L·A·N·T·A
Expanding Horizons
American Pharmaceutical Association
135th Annual Meeting and Exhibit
March 12–16, 1988

DRUG DIVERSION
National Association
of Retail Druggists



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See page 16

The State of Maryland

Proclamation
from the
Office of the Governor

ADVICE TO THE PATIENT DAY

SEPTEMBER 16, 1987

WHEREAS, It is most essential that the consuming public be educated about the proper use of both over-the-counter and prescription drugs, and a new publication entitled "Advice To The Patient" nobly strives to do just that; and

WHEREAS, A key resource in helping our citizens continue on the path to good health is the pharmacist... and Maryland's dedicated pharmacists have once again demonstrated their concern for the people they serve by voluntarily displaying this book in their respective stores; and

WHEREAS, The United States Pharmacopeial Convention, Inc., our nation's heralded standard-setting organization for prescription drugs, has created and distributed this publication... and the proud members of the Maryland Pharmacist's Association and WBAL-Radio and WBAL-TV have joined forces to get the word out about this excellent medical reference material which is readily available for public use; and

WHEREAS, Maryland is pleased to join in congratulating all of the aforementioned parties who have worked hand-in-hand to alert our citizens about this valuable public service effort... and we also join in reminding everyone that "What You Don't Know Can Hurt You."

NOW, THEREFORE, I, WILLIAM DONALD SCHAEFER, GOVERNOR OF THE STATE OF MARYLAND, do hereby proclaim September 16, 1987 as ADVICE TO THE PATIENT DAY in Maryland, and do commend this observance to all of our citizens.

Given Under My Hand and the Great Seal of the State of Maryland.
this 16th day of September.
One Thousand Nine Hundred and Eighty-seven

William Donald Schaefer
Governor

Secretary of State

September 16, 1987 was declared "Advice to the Patient Day" by Maryland Governor William Donald Schaefer in recognition of the successful public education campaign being conducted by the Maryland Pharmacists Association, the United States Pharmacopeial Convention and WBAL-Radio and Television. A proclamation was given to the Association by the Governor in ceremonies held at the Capitol building in Annapolis. Shown receiving the proclamation are (left to right) Philip Weiner, Chairman of MPhA Public Affairs Committee and the spokesman for the public service announcement; William Heller, Executive Director of the USP and MPhA Honorary President for 1986–87; Governor Schaefer; Lee Ahlstrom, MPhA President; and Mark Levi, MPhA Trustee and Chairman of the Medicaid-Pharmacy Liaison Committee.

Governor Schaefer received a copy of the "Advise to the Patient" portion of the USP's Dispensing Information which had been sent to all Maryland Pharmacies. Shortly before this picture was taken, Governor Schaefer looked up several drugs in the publication and expressed his pleasure at receiving this reference material.

The follow-up evaluation survey which was mailed to all Maryland pharmacies showed overwhelming support for the public education project. The results of the survey are being compiled and will be published in a future issue of the *Maryland Pharmacist*. Spurred by the popularity and positive feedback of this project, the Public Affairs Committee is considering extending the effort and making consultation and patient education projects a permanent part of Association activities. Watch for additional information on these projects. Any members with suggestions or ideas related to patient education activities are encouraged to contact the MPhA office.

Text of the MPhA-USP Public Service Announcement

Medicines.

When you take them improperly, you take a risk.
A risk that they won't work . . .
or worse . . . that they may produce serious side effects. That's why it's so important to ask your Pharmacist about your medicine.

Every pharmacy in Maryland now has a special book called *Advice for the Patient*. Use it to look up the drugs you're taking. Find out what they're supposed to do and how to take them properly.
When it comes to medicines, what you don't know *can* hurt you.
A message from the United States Pharmacopeia, WBAL TV and Maryland Pharmacists Association.

First hundreds...

Then thousands...

Soon more than a million.

Soon more than a million insulin users will be taking Humulin.

And no wonder. Humulin is identical to the insulin produced by the human pancreas—except that it is made by rDNA technology.

Humulin is not derived from animal pancreases. So it contains none of the animal-source pancreatic impurities that may contribute to insulin allergies or immunogenicity.

The clinical significance of insulin antibodies in the complications of diabetes is uncertain at this time. However, high antibody titers have been shown to decrease the small amounts of endogenous insulin secretion some insulin users still have. The lower immunogenicity of Humulin has been shown to result in lower insulin antibody titers; thus, Humulin may help to prolong endogenous insulin production in some patients.

Any change of insulin should be made cautiously and only under medical supervision. Changes in refinement, purity, strength, brand (manufacturer), type (regular, NPH, Lente®, etc), species/source (beef, pork, beef-pork, or human), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.

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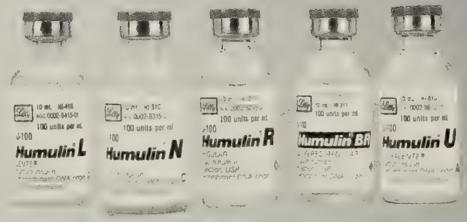

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What Can Your Association Do For You That You Cannot Do Alone?

Plenty

Consider:

Pharmacy's Public image
Medicaid
The State Legislature
Non-Pharmacist Dispensers

Ask Yourself:

How can one person impact these groups?

Then Consider:

More than 1400 Maryland Pharmacists have decided to make their impact by working together in the Maryland Pharmacists Association.

Look at the evidence in this very Journal. The results of a successful public relations campaign to educate the public and improve the image of Pharmacy. The following pages contain valuable information on regulation of dispensing physicians and nurses available to you only through MPhA. A New lobbyist has been hired and the Medicaid dispensing fee was raised to $3.70.

Pharmacists can do even more together. But the MPhA needs every Maryland Pharmacist to strengthen the voice of Pharmacy. The MPhA Needs You.

Mail:

Send your membership dues for 1988 today. Save the MPhA the expense of multiple billing. Urge Non members to join and share the load. Show them this valuable issue of the journal and explain what they have been missing.

YOU ALONE CAN HELP YOURSELF BY WORKING WITH OTHERS.

Maryland Pharmacists Association, 650 W. Lombard Street, Baltimore, Maryland 21201.
Phone (301) 727-0746

SAVE THIS MATERIAL

10.32.15 Dispensing Prescription Drugs by a Licensed Physician

Proposed Regulations
by
The Maryland Board of Medical Examiners

Authority: Health Occupations Article 14-205
Annotated Code of Maryland

.01 Scope.

A. To define the parameters under which a licensed physician may prepare and dispense prescription drugs in accordance with Health Occupations Articles 14-205 and 12-102.

.02 Definitions.

A. The following terms have the meanings indicated.

B. Terms defined.
  (1) ''Administering'' means the provision of a single dosage of a drug at a given time.
  (2) ''Board'' means the Board of Medical Examiners.
  (3) ''Drug Sample'' means a small quantity of a medication packaged by the manufacturer or an authorized agent of the manufacturer for distribution directly by the manufacturer or its agent without charge to a health care provider who is authorized to dispense same to patients without charge and which is intended to be used to initiate therapy.
  (4) ''Licensed physician'' means a physician, including a doctor of osteopathy, licensed by the Board to practice medicine.
  (5) ''Starter dose'' means medication sufficient to initiate therapy designed not to exceed 48 hours of dosage.
  (6) ''In the public interest'' means the dispensing of drugs by a licensed physician for the convenience of the patient.

.03 Exemptions to Dispensing Requirements.

A. These regulations do not prohibit:
  (1) A licensed physician from personally dispensing a drug sample to a patient provided:
    (a) The drug sample complies with the labeling and packaging requirements in H.O. 12-102.
    (b) That no charge is made for the drug sample, and the authorized prescriber enters an appropriate record in the patient's chart.
  (2) A licensed physician from personally dispensing a starter dosage of a prescription drug.
  (3) A licensed physician from administering a prescription drug in the course of treating a patient.
  (4) A licensed physician from dispensing a prescription drug in the course of treating a patient:
    (a) At a medical facility or clinic that specializes in the treatment of medical cases reimbursable through Workmen's Compensation insurance.
    (b) At a medical facility or clinic that is operated on a non-profit basis.
    (c) At a health center that operated on a campus of an institution of higher education; or
    (d) At a public health facility, a medical facility under contract with a state or local health department, or a facility funded with public funds.
  (5) A hospital based clinic from dispensing prescriptions to its patients.

.04 Dispensing Requirements.

A. Physician dispensers may not have a substantial financial interest in a pharmacy.

B. Physician dispensers must comply with labeling, accountability, security, control, recordkeeping and use of safety closure containers in accordance with H.O. 12-102.

C. The prescription drug must be dispensed by the physician.

D. Physician dispensers offices must be open for inspection by the Division of Drug Control.

.05 Application to Dispense.

A. An applicant wishing to dispense prescription drugs must comply with the following:
  (1) Complete an application form provided by the Board affirming:
    (a) That the dispensing privilege is only for the patients of said physican dispenser.
    (b) That the physician dispenser will comply with labeling and security procedures as described in H.O. 12-102.
    (c) That prescriptions dispensed will be duly noted on patient's chart.
    (d) That the charge for the medication will be a separate and distinct entry on the patient's bill.

(e) That the physician dispenser's office will be open to the Division of Drug Control for periodic inspection.

B. The physician shall offer the option of a prescription and post a sign clearly visible to the patient publicizing the option.

.06 Approval to Dispense.

A. Physician may dispense only upon receipt of written approval from the Board of Medical Examiners.

.07 Complaints.

A. On receipts of a written and signed complaint the Commission on Medical Discipline may investigate an alleged violation of these regulations.

STATEMENT OF NURSES' RESPONSIBILITIES IN DISPENSING DRUGS DURING THE ABSENCE OF A PHARMACIST

Approved by the Liaison Committee, Medical and Chirurgical Faculty of the State of Maryland, June 22, 1966.

Approved by the Board of Directors, Maryland Nurses Association, March 28, 1966.

Subsequent to the development of "Protocol on Registered Nurse Responsibilities and Duties as Related to the Medical Practice Act," November 20, 1964; revised May 26, 1965, Dr. John F. Scheafer, chairman, Liaison Committee, Medical and Chirurgical Faculty, at the request of his committee, met with Mr. Frank S. Balassone, secretary, Maryland Board of Pharmacy on February 15, 1966 to discuss item 18 of the protocol.

Item 18 states "Substitute for pharmacist in his absence." This was approved, if no compound of prescription was involved. At the meeting between Dr. Schaefer and Mr. Balassone it was agreed that no one but a pharmacist can substitute for a pharmacist, and it was further agreed that the following mechanism be established for procurement of drugs from a pharmacy in a hospital in the absence of the pharmacist in charge:

"The night nurse supervisor is authorized to utilize the services of the pharmacy under the following conditions:

1. The pharmacist must provide an emergency pharmaceutical kit containing drugs necessary for the peculiar or particular needs of the hospital from the time the pharmacist leaves the hospital until he returns.
2. An appropriate record shall be kept in the pharmacy, which the nurse shall sign, showing the name of the drug withdrawn, the exact amount of each dose, and the total amount of each drug withdrawn.
3. For any drug not included in the emergency pharmaceutical kit, the pharmacist should be called and should provide emergency service in the procurement and dispensing of the drug required."

Selected Portions of The Nurse Practice Act
HEALTH OCCUPATIONS

Subtitle 1. Definitions: General Provisions.

7-101. Definitions.

(a) *In general.*—In this title the following words have the meanings indicated.

(b) *Board.*—"Board" means the State Board of Examiners of Nurses.

(c) *License.*—"License" means, unless the context requires otherwise, a license issued by the Board to practice:
  (1) Registered nursing; or
  (2) Licensed practical nursing.

(d) *Licensed practical nurse.*—"Licensed practical nurse" means, unless the context requires otherwise, an individual who is licensed by the Board to practice licensed practical nursing.

(e) *Practice licensed practical nursing.*—"Practice licensed practical nursing" means to perform in a team relationship an act that requires specialized knowledge, judgment, and skill based on principles of biological, physiological, behavioral, or sociological science to:
  (1) Administer treatment or medication to an individual;
  (2) Aid in the rehabilitation of an individual;
  (3) Promote preventive measures in community health;
  (4) Give counsel to an individual;
  (5) Safeguard life and health;
  (6) Teach or supervise; or
  (7) Perform any additional acts authorized by the Board under §7-205 of this title.

(f) *Practice registered nursing.*—(1) "Practice registered nursing" means the performance of acts requiring substantial specialized knowledge, judgment and skill based on the biological, physiological, behavioral or sociological sciences as the basis for assessment, nursing diagnosis, planning, implementation and evaluation of the practice of nursing in order to:
  (i) Maintain health;
  (ii) Prevent illness; or

(iii) Care for or rehabilitate the ill, injured, or infirm.

(2) For these purposes, "practice registered nursing" includes:

(i) Administration;

(ii) Teaching;

(iii) Counseling;

(iv) Supervision, delegation and evaluation of nursing practice;

ANNOTATED CODE OF MARYLAND

(v) Execution of therapeutic regimen, including the administration of medication and treatment;

(vi) Independent nursing functions and delegated medical functions; and

(vii) Performance of additional acts authorized by the Board under §7-205 of this title.

(g) *Registered nurse.*—"Registered nurse" means, unless the context requires otherwise, an individual who is licensed by the Board to practice registered nursing.

7-102. Scope of title.

(a) *"Christian Science nurse" defined.*—In this section "Christian Science nurse" means an individual who is registered as a Christian Science nurse in the Christian Science Journal of the Christian Science Publishing Society.

(b) *Conduct not prohibited.*—Except as specifically provided in this title, this title does not limit the right of:

(1) An individual to practice a health occupation that the individual is authorized to practice under this article;

(2) A Christian Science nurse to care for an individual who is ill, injured, or infirm, if the Christian Science nurse does not administer any drug or medicine; or

(3) An unlicensed individual to perform acts of registered nursing or acts of licensed practical nursing:

(i) While supervised by an individual who is authorized by this State to practice medicine, dentistry, registered nursing, or licensed practical nursing; and

(ii) If the unlicensed individual performs only acts that are in the area of responsibility of the supervisor and under the instruction of the supervisor.

Subtitle 2. State Board of Examiners of Nurses.

7-201. Board established.

There is a State Board of Examiners of Nurses in the Department.

Definition of "Administration"

from the Maryland Board of Nursing

Under the Nurse Practice Act, the definition of "practice of registered nursing" includes "execution of a therapeutic regimen, including the administration of medication and treatment". Similarly, the definition of "practice licensed practical nursing" includes "administer(ing) treatment or medication to an individual". "Administration" has been defined by the State Board of Examiners of Nurses as:

> "the direct introduction to a designated patient of a single dose of a prescribed medication at a given time".

It is legal only for the nurse to take from a properly labeled container a single dose of the prescribed medication for a particular patient. Administration does not include dispensing of medications or the prescribing of medications.

Dispensing is governed by the Maryland Pharmacy Act. The definition of drug dispensing provided below is intended to assist the nurse in differentiating between administration and dispensing of medications.

> "According to Swafford drug dispensing involves one of three things: (1) the issuance of one or more doses of a medication in containers other than the original, such as new containers being properly labeled by the dispenser as to contents and/or directions for use as indicated by the prescriber. (2) Drug dispensing is the issuance of medication in its original container with a pharmacy-prepared label that carries to the patient the directions of the prescription as well as other information. And (3) drug dispensing occurs where the container carries a pharmacy prepared label and the container is intended for nursing station use in a hospital or nursing home."[1]

More specifically, to issue medication in a container which requires labeling and which is intended for other than immediate use is dispensing.

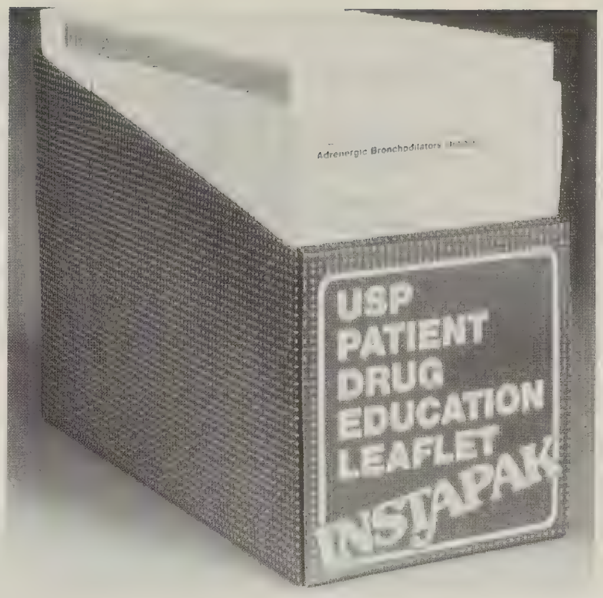
Prescribing is governed by the Medical Practice Act. Prescribing can be defined as designation of the use of a specific therapeutic agent. This action is not within the scope of practice of the registered nurse and licensed practical nurse.

If a nurse has questions regarding the functions the nurse has been asked to perform and their relationship to the Nurse Practice Act, he or she should contact the State Board of Examiners of Nurses.

---

[1] Creighton, Helen: "Law Every Nurse Should Know.", W. B. Saunders Co., 1975, p. 285

Richard S. Dallow was appointed to the position of Vice President of Operations for The Drug House. He has over 24 years of experience in the drug wholesale business.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Pharmacy Students Sherine O. Aly (left) and Carole L. Filowitz (right) recently completed an eleven-week structured internship at Merrell Dow Pharmaceuticals in Cincinnati. Aly attends the Philadelphia College of Pharmacy and Filowitz attends the Rutgers University College of Pharmacy. Both students are in their final year.

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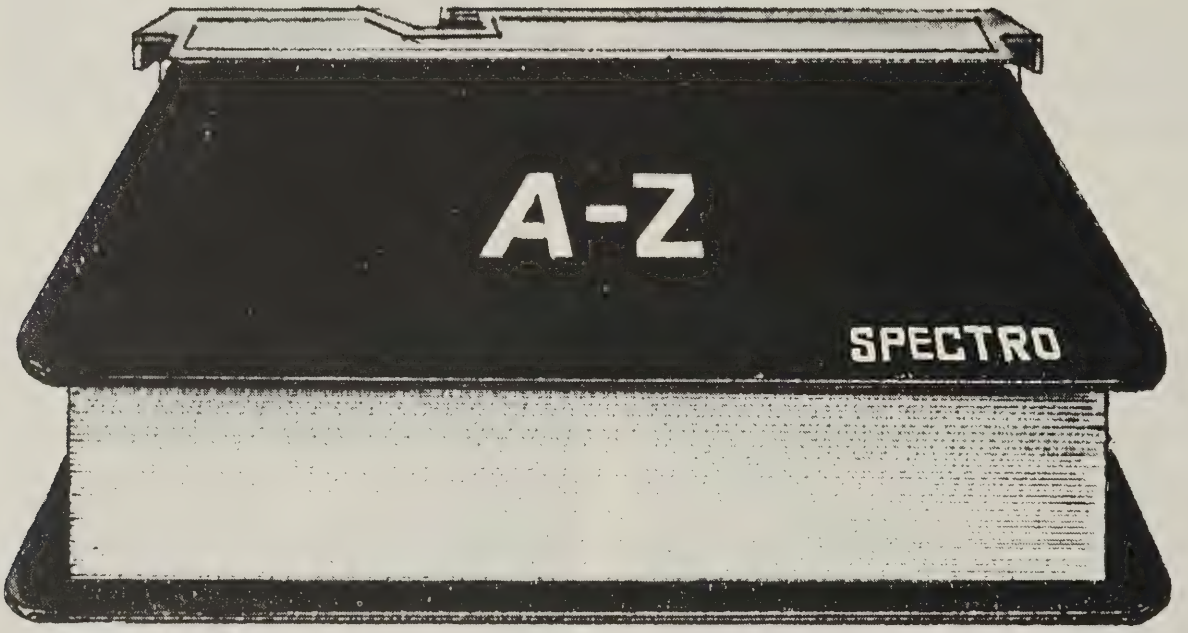

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The Young Pharmacists Caucus is making available a short reference list for the Maryland Formulary. Bradley Thomas deserves credit for putting it together. Copies can be had by sending a self addressed stamped business size envelope to the MPhA with your request.

PHARMACIES

Several small prescription-oriented pharmacies are currently available for individual ownership in the State of Maryland. These opportunities provide the vehicle to practice pharmacy the way you were taught, while offering an attractive income and more time to be with your family. For more information write: Jan Patrick, 10121 Paget Drive, St. Louis, MO 63132

Maryland Society of Hospital Pharmacists Meetings

MARK YOUR CALENDARS, PLEASE:

The 1987–1988 MSHP Roster of Monthly Programs is under development. Please note the following dates and sites on your calendars:

NOVEMBER 12, 1987	University of Maryland Medical System
DECEMBER 3, 1987 (note *first* Thurs!)	Franklin Square Hospital
* JANUARY 14, 1988	* SPECIAL AGENDA at a Non-Hospital Site (TBA) will feature Officers' Installation *
FEBRUARY 11, 1988	—TBA (To Be Announced)
MARCH 10, 1988	—TBA (To Be Announced)
APRIL 14, 1988	Mercy Hospital
MAY 12, 1988	Johns Hopkins Hospital

PHARMACY SCHOOL NATIONAL TOLL FREE PHONE LINE. The school of Pharmacy has acquired a new national toll free phone for Admission and Registrar department. The number is 1-800-832-2988, you may call between the hours of 9:00 a.m. and 5:00 p.m., Monday–Friday. The new 1988 Pharmacy School catalog is now available for order.

calendar

November 5—BMPA annual meeting and election of officers
November 8—CECC Seminar on Hypertension at the School of Pharmacy
November 12—MSHP regular meeting
November 18—AZO evening meeting
December 3—MSHP regular meeting
January 4—State Legislature Begins 1988 session
Jan. 22–24—MPhA and Alumni Assn. Ski Weekend
February 7—MPhA Mid Year Meeting—Annapolis
March 12–16—APhA Annual Meeting—Atlanta

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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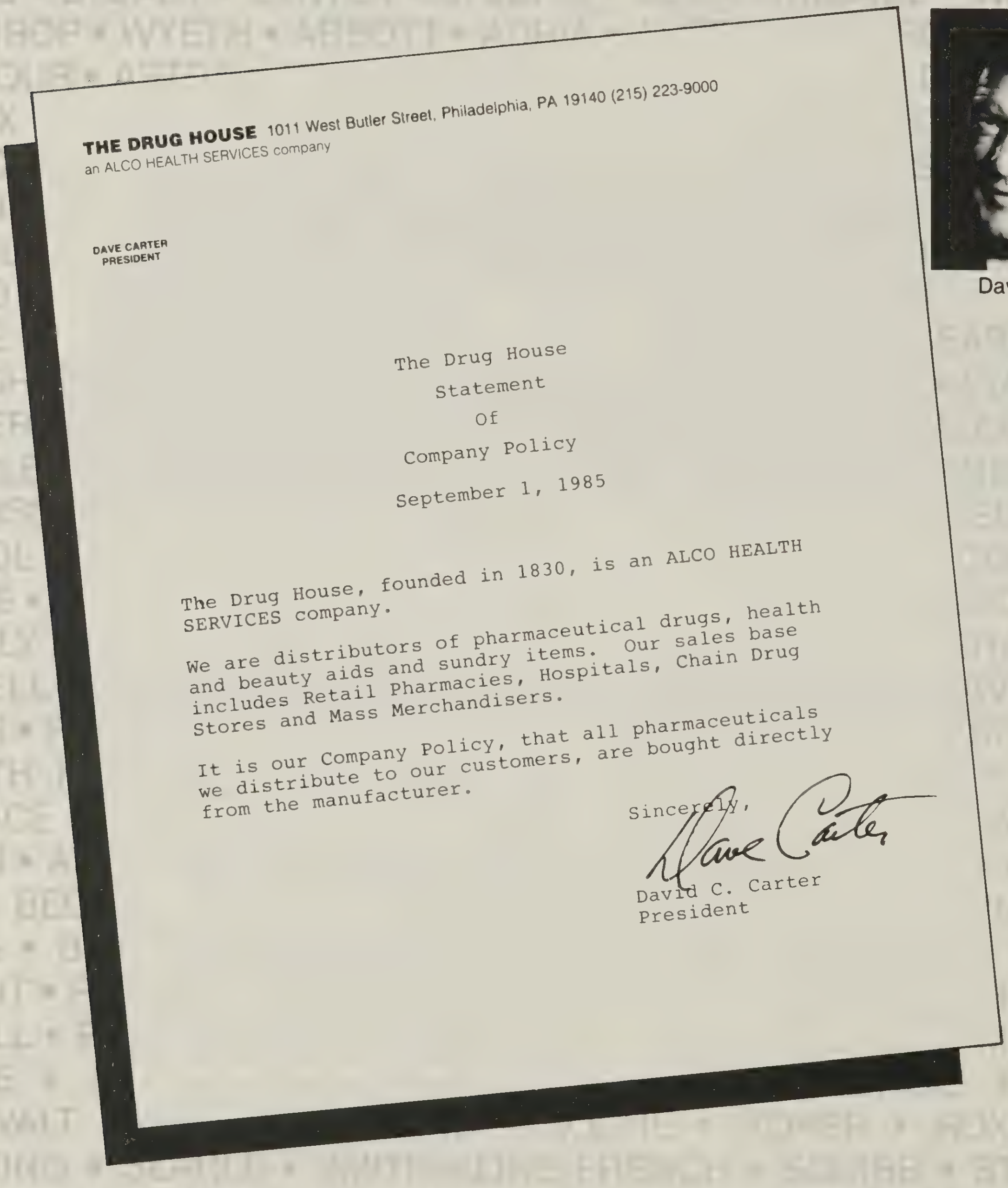

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Dave Carter

David C. Carter
President

David C. Carter,
President

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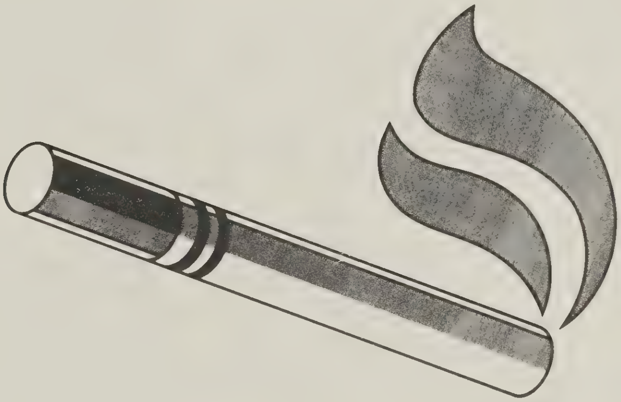
VOL. 63
NO. 12

Special Issue on Smoking



Advising Consumers on OTC Smoking Deterrents

— J. Richard Wuest
— Thomas A. Gossel

The Pharmacist and Hospice

— Diane White
— Lynda H. Oderda
— Ilene H. Zuckerman

Polymedicine and the Elderly

— Peter P. Lamy

New Face of Pharmacy—A Commentary

— Jim Dickinson

THE MARYLAND PHARMACIST

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GUEST PRESIDENT'S MESSAGE

DELEGATE PRIDE

As required by resolution of the House of Delegates at the 1987 Annual Meeting the Constitution and Bylaws of the Association are being revised to reflect major changes in the Association, and Pharmacy in general, since the last revision. After approval by the Board of Trustees the House of Delegates will first consider and then vote, at two separate meetings, on the proposed changes. If accepted, the composition of the House of Delegates will change.

Under the new proposals there will be more equal representation from local, affiliated, and recognized organizations. Also, the burden of filling up the delegate positions will be shifted from MPhA staff to the elected officers.

Being a delegate to the House of Delegates is an honor and a responsibility. As a delegate you are representing the affiliated or recognized organization that elected or appointed you. This position carries a large importance in our Association. After all, it is through our policy-making body, the House of Delegates, and through policy statements, resolutions, that our Association decides future goals and directions, legislative initiatives, or official stands or opinions on pertinent issues. When a resolution states that continuing education should be mandatory for all pharmacists then our state association has officially endorsed that idea.

Under the proposed changes there will be a limited number of delegates, between 70 and 80. Only delegates may vote for passage or failure of resolutions.

Furthermore, the House of Delegates is charged with approving the slate of candidates for election of officers and board members. Delegates approve or disapprove this slate, or add to it. Also on this slate is the Association's recommendations for the Board of Pharmacy commissioners. This important function helps shape the leadership of the Association.

Lastly, the House of Delegates elects its own officers, Speaker and Vice-Speaker, which represents it to the Board of Trustees.

The message here is that being a Delegate is a duty, a responsibility; not just who shows up at the meeting. What we are looking for in our delegates is a committment. We are looking for our members to petition their respective locals to become delegates or to petition the Speaker of the House for one of the Delegates-at-large positions.

We are looking for some good men and women.
The Few
The Proud
The Delegates

Brian T Sanderoff

Speaker of the House of Delegates

CONTINUING EDUCATION FOR PHARMACISTS

STATE CONSORTIUM ON PHARMACEUTICAL EDUCATION • VOL. IV, NO. 11

Advising Consumers on OTC Smoking Deterrents

by J. Richard Wuest, R.Ph., Pharm.D.
Professor of Clinical Pharmacy
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and Toxicology
Ohio Northern University
Ada, Ohio

Goals

The goals of this lesson are to:

1. discuss the pharmacology and therapeutics of smoking deterrents; and
2. provide information for consumers who wish to use a smoking deterrent product.

in the service of pharmacy

This continuing education for Pharmacy article is provided through a grant from

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Objectives

At the conclusion of this lesson, participants will be able to:

1. list OTC smoking deterrent product ingredients and state their mechanism of action;
2. state the requirements for a smoking deterrent to be effective;
3. select from a list of adverse effects, those reported for a specific smoking deterrent; and
4. discuss specific points of information for properly using smoking deterrents.

Before the 1960's, smoking in public places was viewed as a somewhat fashionable and socially acceptable practice. Since then, medical and social pressures on smokers to quit have increased as a result of reports linking smoking with bronchopulmonary disorders, coronary artery and peripheral vascular diseases, lung cancer and peptic ulcer. Added to this are nonsmokers demanding the freedom to breathe air that is not "polluted" with smoke from another person's bad habit.

In 1964, the famous "Cigarette smoking may be dangerous to your health" statement was published by the Surgeon General. Its appearance on all cigarette packages and advertising materials was mandated. Since then, the percentage of Americans who smoke has dropped from 42 percent to less than one-third of the adult population.

It is not easy for a smoker to quit. National survey data indicate that at least 30 percent of all smokers in this country have tried to stop smoking, at least once, with only 20 percent of them successful after several months. Even after the best smoking cessation programs, a large number of smokers return to previous patterns within a few months. The term *recidivism* describes the inability to refrain from smoking after a period of abstinence.

Evidence to support any long-term success rate for smoking cessation (i.e., a year or longer) with available self-treatment methods is lacking. Short-term success has been occasionally reported for counseling and hypnotism, aversion and deprivation, motivational programs and public service education.

There are three basic factors to overcome to be successful with smoking cessation. The first is a highly intense *pharmacologic* need which persists several hours after exposure to nicotine.

The second factor is a *psychological* craving that includes the need for oral gratification. This is reported to be less intense than the former factor, but it is implanted in the subconscious mind and may persist for years.

The third component is the *social pressure* that led the person to begin smoking in the first place.

Over the years, a variety of "home remedies" and proprietary products have been snuffed, sucked, chewed or swallowed in an attempt to help reduce the urge to smoke. Substances such as dried lettuce leaves, corn silk, and coffee grounds have been rolled into cigarettes or stuffed into pipes. It is apparent that the majority of smokers who try to quit are merely "between cigarettes."

OTC Smoking Deterrents

Over-the-counter smoking deterrent products work in one of two ways. The first is to impart a disagreeable flavor to tobacco smoke so that smoking becomes less pleasant.

The second is to substitute another drug, taken orally, that has nicotine-like pharmacologic action but easier withdrawal. The smoking habit and psychological craving can, therefore, be broken.

TABLE 1

Substances Reported to be Smoking Deterrents

Aloin
Aluminum chloride
Aluminum hydroxide
Belladonna
Benzocaine
Capsicum
Cascara sagrada
Chlorophyllin
Cloves*
Cimicifuga
Coriander*
Eucalyptus*
Gentian
Hawthorne
Lemon oil*
Licorice root*
Lobeline*
Menthol*
Methapyrilene
Methyl salicylate*
Niacin
Nux vomica
Pyridoxine
Quinine ascorbate*
Silver acetate*
Silver chloride
Silver nitrate*
Sodium ascorbate
Thiamine
Thymol*

*reported to aid in *stopping* smoking rather than smoking less.

During its review of OTC smoking deterrents, the FDA Advisory Panel on OTC Miscellaneous Drug Products evaluated the currently available ingredients. The panel limited its evaluation to ingredients that manufacturers claimed aided an individual in *stopping* smoking (those with an asterisk in Table 1). The panel felt that products which assisted in *reducing* smoking were not only ineffective smoking deterrents, but were also a waste of consumers' time and money.

The panel could not find adequate evidence of safety and effectiveness for most of these substances. Lobeline and silver acetate were classified as potentially promising. Both were safe; neither was proven effective.

FDA announced in July, 1985, that it concurred with the panel's recommendation. The agency stated that unless satisfactory proof of efficacy was forthcoming, these OTC products would be removed from the market. The agency also stated that it would "close the books" on OTC smoking deterrents in September, 1986, and that manufacturers had until then to submit proof of efficacy. Accordingly, manufacturers asked for an extension of this deadline. FDA granted it since data collected so far appear favorable.

Recently, a manufacturer requested that a combination product, povidone-silver nitrate, in a mouth rinse dosage form be ruled safe and effective as an OTC smoking deterrent. FDA answered that since no such product had ever been marketed and used in this country, and since it was not submitted to the advisory panel for review, the agency would consider it only if submitted as an NDA that included proof of safety and efficacy. So, the door is still open for this product to enter the marketplace if its manufacturer succeeds in its clinical trials.

OTC Smoking Deterrent Labeling

Besides ruling on the safety and efficacy of OTC ingredients, FDA also has the responsibility to assure that claims by the manufacturers and product labeling are truthful and not misleading. The panel that reviewed these products recommended, and FDA accepted with a few relatively minor revisions, that a smoking deterrent should be defined as "A substance that is used temporarily to help those individuals who want to stop smoking (or, become cigarette-free) or to break the cigarette habit."

Interestingly, there were a number of significant differences of opinion between FDA and its panel concerning the actual claims that can be made by manufacturers. The panel recommended acceptance of all claims listed in Table 2. FDA stated that use of the word "temporarily" in the phrases "Helps you stop cigarette urge — temporarily," and "Helps you stop smoking cigarettes — temporarily" is confusing and does not adequately reflect the intended use of smoking deterrents. While deterrents are used *temporarily*, the intention is to stop smoking *permanently*. Therefore, FDA deleted these two indications from the allowable claims and left (a) and (b) of Table 2 remaining.

The agency also deleted the statement suggested by the panel, "This product's effectiveness is directly related to the user's motivation to stop smoking cigarettes." FDA believed that the statement for "Temporary use to help those individuals who want to stop smoking, become cigarette free or to break the cigarette habit" is adequate. The agency stated that the recommended statement was repetitive and, therefore, unnecessary.

TABLE 2

Allowable Labeling Claims for OTC Smoking Deterrents*

Indications:

a. A temporary aid to those who want to stop smoking.
b. A temporary aid to breaking the cigarette habit.
c. Helps you stop the cigarette urge temporarily.**
d. Helps you stop smoking cigarettes temporarily.**

Required Statement**
This product's effectiveness is directly related to the user's motivation to stop smoking cigarettes.

*As determined by an FDA/OTC advisory panel.
**These indications/statements were rejected by FDA.

Safe and Possibly Effective OTC Smoking Deterrents

Lobeline (e.g., Bantron, Nicoban). The alkaloid is obtained from the Lobelia plant, which is also known by various names including asthma weed, bladder pod, emetic herb, Indian tobacco, vomit weed, and wild tobacco. The name "Indian tobacco" was given to it because it was once believed to have been used by Indians as a substitute for tobacco. It is questionable whether American Indians actually did smoke the substance.

The most commonly employed form of lobeline is the sulfate salt. It produces similar neuropharmacologic actions as nicotine on the peripheral circulation, neuromuscular junction and central nervous system. The effect is much weaker and less toxic.

Evidence of lobeline's effectiveness as a smoking deterrent looks good on the surface. However, by late 1986, data had still not been collected as required in efficacy studies. One well documented and placebo-controlled study involved 200 chronic smokers. Eighty percent of them stopped smoking after 5 to 6 days therapy using doses of 2 mg three times a day. This compared to only 10 percent of individuals in the placebo group who stopped smoking.

Other studies have failed to show that lobeline is an effective smoking deterrent at the recommended dose. Nevertheless, since most have shown promising results, FDA is permitting further testing before a final judgement is made.

Lobeline's principle pharmacologic actions are on autonomic ganglia, the vomiting and respiratory centers. It was formerly employed as an emetic. In the early 1900's, it was used to stimulate breathing after overdosage with respiratory depressants.

A single dose of 8 mg has been reported to cause belching, epigastric pain, severe heartburn, nausea and vomiting, and fainting. Higher doses have produced arrhythmias, muscular twitching, convulsions and death from respiratory paralysis.

The 2 mg OTC dose is rarely associated with adverse effects. One study employing 2 mg three times a day showed no effect on heart rate, blood pressure, or respiration in 23 healthy subjects, 17 to 43 years of age. Several other studies have also failed to demonstrate evidence of toxicity resulting from use of up to six weeks. Taking an antacid with the product may lessen the occurrence of epigastric effects. This has not yet been proven.

Lobeline sulfate is safe for self-administration at a dose of 2 mg three times a day for periods up to six weeks. Since there are no chronic toxicity studies, labeling of OTC products containing lobeline must include the warning "Do not use this drug for longer than six weeks." In order to claim that the product can be used longer than six weeks, a manufacturer must conduct the required studies.

Silver Acetate (e.g., Healthbreak). Silver acetate clings to oral mucosa. Tobacco smoke reaches this and imparts an objectionable "metallic-sweet" taste which persists up to 4 hours. Smoking, therefore, becomes less desirable. Theoretically, this activity meets the requirements of an effective OTC smoking deterrent.

However, there have been no scientifically acceptable studies to prove that silver acetate is an effective smoking deterrent. The results of several tests *suggest* that it is effective, but the data are neither consistent nor reproducible. For example, a 2-week study involving 50 subjects assessed the average number of cigarettes smoked by a treatment group and a placebo group on days 13 and 14 to verify the effectiveness of the deterrent. Average values were 10.6 cigarettes for the treatment group, and 18.4 for the placebo group, respectively. There was no mention of how many people actually stopped smoking, or how the data were obtained.

Another survey reported on 617 smokers who used either a silver acetate product or placebo. They received the preparation by mail followed by a questionnaire 4 to 5 weeks later. Responses were also returned by mail. Thirty percent of the silver acetate group, versus 25 percent of the placebo group, reported that they had stopped smoking. The difference was marginally significant. No further information about the study was presented.

The problem with many studies on OTC smoking deterrents is that they are uncontrolled or poorly controlled without objective measurements. Few have used long-term follow-up. Most reports are based on unverified statements by subjects who do not mention the number of cigarettes they smoke. There are rarely ever blood checks to measure nicotine, carbon monoxide, or levels of other substances known to be present following smoking. Therefore, to accurately assess the reliability of any OTC smoking deterrent, manufacturers are now required to closely follow an established protocol based on sound scientific principles. In the meantime, products that contain lobeline and silver acetate can continue to be marketed as long as manufacturers undertake the required clinical studies.

On the safety side, silver acetate has no known undesirable side effects other than mild discoloration of skin and mucous membranes. This occurs in much higher concentrations than are present in OTC smoking deterrents.

Animal studies involving doses several times higher than the human dose have failed to produce additional adverse symptoms. The FDA/OTC advisory panel found that a dose of 6 mg silver acetate in a chewing gum base used every 4 hours, up to six doses in 24 hours, was safe. It further advised that a warning label be included on products containing silver acetate: "Do not use this product longer than three weeks. Frequent or prolonged use of this medication may result in permanent discoloration of the skin or mouth."

Nicotine Polacrilex Gum (Nicorette®)

While it is not an OTC item, a discussion of smoking deterrents would not be complete without reviewing one proven product — Nicorette®. This chewing gum dosage form of nicotine was developed in Sweden in the mid-1960's. It was designed to maintain plasma nicotine levels that would help satisfy an individual during a smoking cessation effort, while coping with the oral gratification and other psychological aspects of smoking. Nicorette® consists of the natural nicotine extract of the tobacco plant buffered to pH 8.5 for enhancement of buccal absorption.

Each piece of gum contains 2 mg of nicotine bound to an ion-exchange resin. Approximately 90 percent of the nicotine is released slowly over a 30-minute period of normal chewing. The rate is uniquely controlled by the rapidity with which a person chews the gum. Therefore, an individual can control the amount of drug available for absorption by altering the rate of chewing.

Efficacy studies have shown that Nicorette® can approximately double the success rate of placebo in a smoking cessation program. For example, results of one study demonstrated that 47 percent of Nicorette® users, versus 21 percent of a placebo group, were still abstinent one year after treatment. Even more impressive, is that 31 percent of the Nicorette® group, versus 14 percent of the placebo group, did not smoke at all since the start of their treatment, to the follow-up period one year after stopping smoking. All Nicorette® users reported much less severe nicotine withdrawal symptoms from the gum than from smoking, as compared to the placebo group.

Sufficient evidence has accumulated to show that smoking is a true addiction rather than merely a "nasty habit." It produces a frank withdrawal syndrome that is related to nicotine. Inhaling cigarette smoke directly into the lungs causes a rapid rise of blood and brain nicotine levels (within 7 seconds), providing a "rush" that the body begins to rely on after a relatively short time. Deprived of nicotine, the body reacts by craving it and reacting adversely if it is not forthcoming.

Unlike other smoking deterrents currently available, Nicorette® produces plasma nicotine levels which correlate with those obtained with cigarette smoking. After first removing oneself from the physical habit of smoking, a person can then withdraw from the addiction to nicotine more easily.

Adverse effects related to nicotine gum are generally mild in smokers. Those that have been reported include dizziness, sore mouth, nausea and stomach pain. They usually subside quickly with continued therapy in most individuals.

What happens if the gum is swallowed? The answer is simply, "very little." This is because nicotine is poorly released from the gum base without chewing. That which is released in the gastrointestinal tract and absorbed is quickly metabolized and inactivated by hepatic enzymes. Nonetheless, the product is provided in a child-resistant package to help deter accidental poisonings.

Overview

Smoking is a major social problem in that it causes or worsens a number of health conditions. It also results in a true addiction to nicotine. It is estimated that approximately one-third of all smokers have tried to stop smoking, but most resume their habit after only a few months. Thus, a smoking deterrent that would be both safe and effective would be most welcome.

Lobeline and silver acetate are safe for self-medication, but neither has been shown (at the time of writing of this article) to be effective. Perhaps their efficacy will be confirmed in the future. Meanwhile, since they are safe, they can continue to be marketed.

The prescription drug Nicorette® has demonstrated both safety and effectiveness. Like all drugs, it must be used correctly to be maximally effective and safe. Important advice for Nicorette® users is listed in Table 3.

TABLE 3

Advice for Patients Using Nicorette® Gum

- Chew the gum slowly. Keep the saliva in your mouth for at least a minute before swallowing.
- Carry Nicorette® gum with you so that it is readily available during your smoking cessation program.
- Chew a piece of gum whenever you feel the urge to smoke. However, do not use more than what your doctor recommends.
- For success in your smoking cessation program, you must abstain from smoking and gradually decrease the use of this gum over a period of several months.
- After you have finished your program and you have stopped smoking, keep some Nicorette® handy in case you get a sudden urge to smoke. Ask your pharmacist how long the gum will maintain its potency (i.e., the expiration date on the package).
- The gum is sugar-free and does not stick to most dentures. If you have problems, brush your dentures before using the gum. Drinking cold water before chewing is helpful since the gum is more likely to stick to warm teeth.
- If you experience side effects such as light-headedness, nausea, or hiccups, you are probably chewing the gum too rapidly.
- If you accidentally swallow a piece of Nicorette® gum, do not be overly concerned; it should pass on through your body and it will not harm you.
- Keep this product out of the reach of children. If a child swallows one or more pieces of the gum, call your doctor or poison control center.

Editor's Note As part of this special issue of *Maryland Pharmacist*, we urge you to use the form to the right to order the kit of information to help patients stop smoking. In addition, use the patient information leaflet on page 9.

Drugs and cigarettes may not mix...

do your patients know?

The American Pharmaceutical Association and the National Cancer Institute introduce a new program to help you explain smoking-drug interactions to your smoking patients . . . and to help them break the habit.

The "Helping Smokers Quit" kit contains a pharmacist's guide, posters, counter card, and enough take-home materials for 25 patients.

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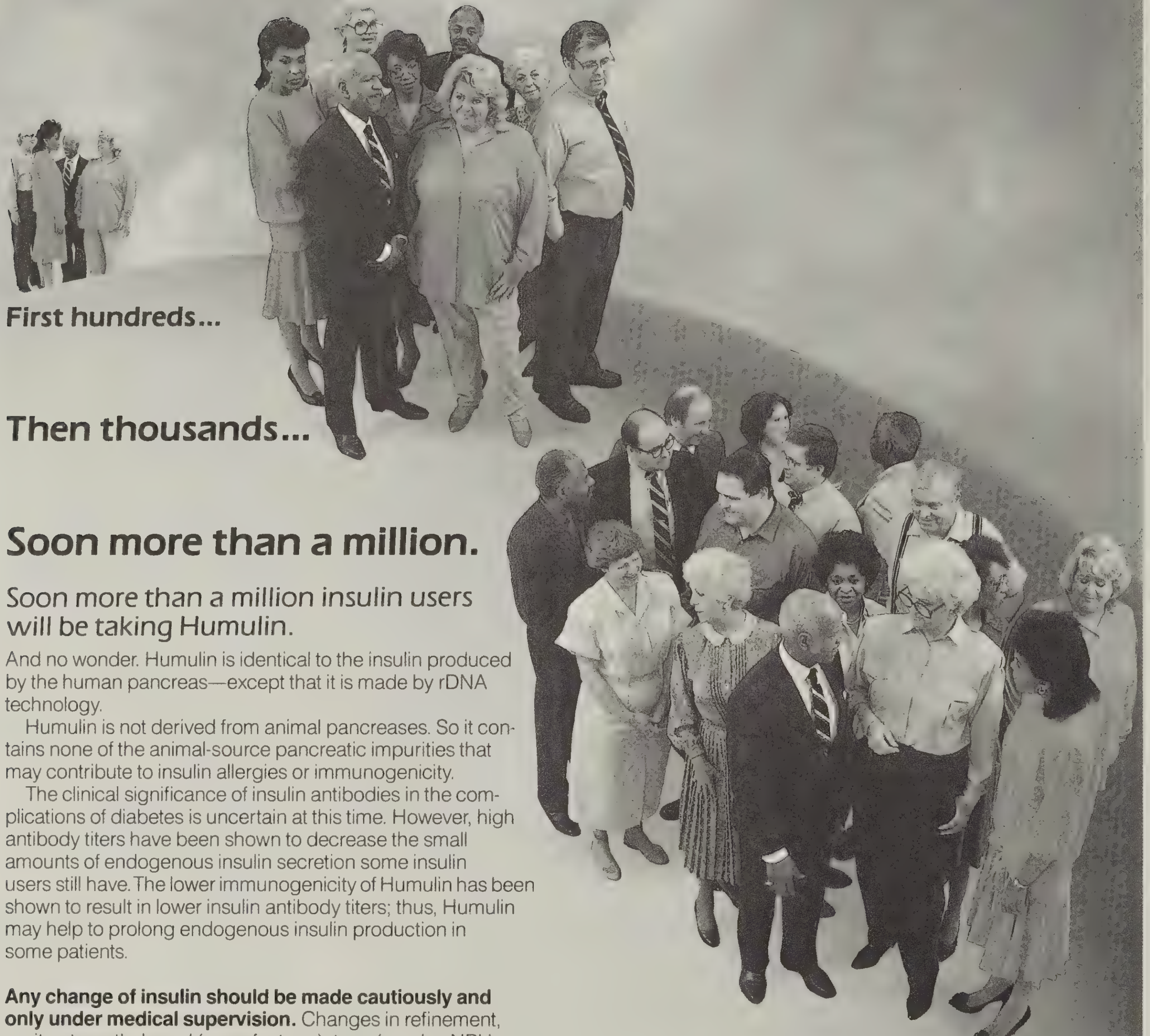

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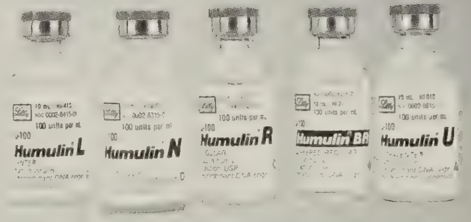

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The "For Your Good Health" leaflet to the right is presented by the MPhA Public Affairs Committee. Members may use this patient education series as bag stuffers or newsletter material.

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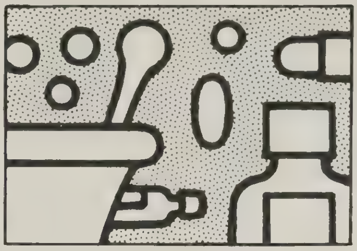
Things You Should Know FOR YOUR GOOD HEALTH



Another Reason Not to Smoke

Recent scientific findings show that cigarette smoking can reduce the effectiveness of some medications as well as worsen existing health problems, complicating drug therapy.

The most common effect of tobacco smoke on drugs in humans is an increase in the rate at which the compounds are chemically altered by the body. Most of the alterations in drug effects in patients appear to involve stimulation of certain enzymes in the liver, where most drugs are metabolized. Of the more than 3,000 compounds found in cigarette smoke, a certain class of particulate compounds known as polycyclic aromatic hydrocarbons (PAH) are thought to be responsible for activating these enzyme systems.

As a result, smokers may require larger or more frequent doses than non-smokers of some medications that are metabolized in the liver. Tolerance to certain drugs after prolonged use also can be enhanced by the additional enzyme induction due to smoking.

A second, potentially important set of interactions could arise from the interactions of drugs with nicotine, the addictive component of tobacco.

The following drugs are those that most clearly interact with cigarette smoke either to increase health risk or to inhibit therapeutic response.

Oral Contraceptives — Smoking increases the risk of serious cardiovascular side effects. Risk increases with age and with the number of cigarettes smoked per day and is quite marked in women more than 35 years of age. Patients using oral contraceptives should quit smoking or select another form of contraception.

Theophylline (anti-asthmatic drug) — Eliminated much more rapidly by smokers, who may require up to two times the maintenance dose of nonsmokers.

Propranolol and Nifedipine (anti-anginal drugs) — Smoking decreases the expected therapeutic effect in treating angina pectoris.

Propoxyphene, Pentazocine and Phenylbutazone (pain killers) — Decreased effectiveness in smokers, who may obtain better relief with larger or more frequent doses or with other analgesics.

For the following additional medications and vitamins, the clinical importance of observed smoking-drug interactions is likely or possible but has not yet been firmly established. Still, there is enough evidence of interaction to warrant caution.

Phenothiazines (tranquilizers) — Effectiveness may be decreased in smokers.

Tricyclic antidepressants — Smokers may have much lower blood levels.

Benzodiazepines (antianxiety drugs) — May be less effective in smokers.

Amobarbital (sedative) — Eliminated much more rapidly by smokers.

Heparin (anticoagulant) — Eliminated more rapidly by smokers.

Furosemide (diuretic) — Diuretic response lower in smokers.

Vitamins — Vitamin B_{12} and C metabolized much more rapidly.

In addition to these direct drug interactions, smoking may adversely affect the following diseases and conditions, making drug therapy more difficult: allergy, angina pectoris, diabetes mellitus, hypertension, pulmonary diseases, ulcers, and vascular disease.

© SPEA

Continuing Column

The Pharmacist and Hospice

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IX
III
VI

IT IS FRIGHTENING TO WALK THIS WAY ALONE—
CAN YOU GO JUST PART OF THE WAY WITH ME?

Anonymous

by Diane White, P.D., Lynda H. Oderda, Pharm.D., Ilene H. Zuckerman, Pharm.D.

MANAGEMENT OF NAUSEA AND VOMITING

The last two articles have focused on medications used in the management of nausea and vomiting associated with cancer chemotherapy. For this last article on this three part series, recent studies of antiemetic therapy will be reviewed, while focusing primarily on the widely used drug, prochlorperazine (Compazine).

The number of antiemetic studies in patients receiving cancer chemotherapy has increased markedly over the past several years. It has already been mentioned that high-dose IV metoclopramide, THC and prochlorperazine are useful antiemetic agents, but studies indicate that one may be preferred over the other when different cancer agents are involved. For example, several studies cited in the January 1984 issue of Cancer Treatment Reports shows that metoclopramide (1–2 mg/kg) was superior to THC against cisplatin-induced nausea and vomiting but suggests that against less emetogenic agents, the two therapies may be similar in efficacy and toxicity. Another study (1985) compared metoclopramide with prochlorperazine. High-dose intravenous metoclopramide and prochlorperazine were similar and effective in the management of cisplatin-induced emesis. Prochlorperazine was effective when administered intravenously at 20 mg dosage. Drowsiness was the most common adverse effect for both regimens.

Prochlorperazine has been the most frequently used agent in the United States for treatment of nausea and vomiting produced by chemotherapy. Clinically, all of the phenothiazines have some antiemetic activity. Evidence of studies done with phenothiazines indicate that they exert their antiemetic activity by blocking dopamine receptors in the chemoreceptor trigger zone. The choice of one phenothiazine over another is usually based on their relative potential for side effects at equipotent doses. Phenothiazines with a piperazine side chain such as prochlorperazine have greater predicted antiemetic activity, but also lead to increased extrapyramidal reactions when compared to those with aliphatic side chains (chlorpromazine).

The drugs that are effective as antiemetics are the antidopaminergic agents (phenothiazines, metoclopramide). Anticholinergic agents such as meclizine, diphenhydramine and dimenhydrinate or agents such as trimethobenzamide and scopolamine may be more appropriate in motion sickness and labyrinthine disorders. Trimethobenzamide has been used for many years as an antiemetic, but evidence of its efficacy is controversial. While some studies demonstrated relief in the subjective feeling of nausea, other studies showed only a 30% relief in patients being treated with trimethobenzamide as compared to 80% efficacy with the use of phenothiazines. Based on the results of such studies, trimethobenzamide cannot be recommended as an effective antiemetic in chemotherapy-induced nausea and vomiting.

Several recent studies have reported useful antiemetic results with corticosteroids. Dexamethasone and methylprednisolone have been used the most frequently for this purpose. Whether the mechanism of antiemetic activity is due to a direct action of the drugs or is due to a feedback inhibition is unclear. It should be noted that this property is an unlabeled use of corticosteroids. Two studies in patients receiving cisplatin have compared dexamethasone with metoclopramide. In one trial, metoclopramide was superior to dexamethasone, but both agents were effective antiemetics. In the second study in which metoclopramide was given orally, equivalent activity for both agents was observed. Corticosteroids may prove most valuable as an adjunct to other antiemetic therapy.

MISCELLANEOUS NOTES

The recommendation for dietary fiber is 6–16 grams of fiber daily. The average American diet contain only *4 grams* per day.

Bran is an excellent source of fiber.

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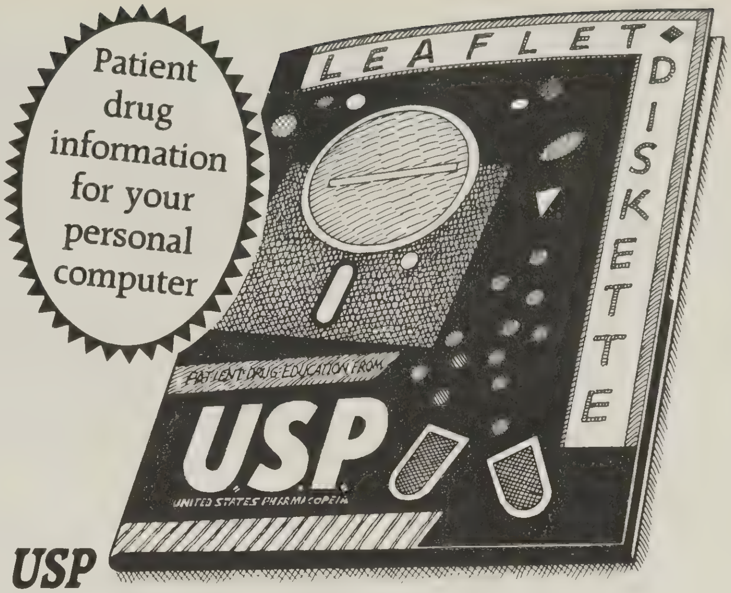
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POLYMEDICINE* AND THE ELDERLY

by Peter P. Lamy, PhD

THE ELDERLY

There are approximately 22 million persons between the ages of 55 and 64 years and 27 million 65 years old and over. Those 49 million people account for 21% of the American population. Those 60 and over account for 17%, and those 65 and over account for 12%. It is important to realize that the aging population itself is aging, those 85 years old and over constituting the fastest-growing segment of the US population.

THE HEALTH STATUS OF THE ELDERLY

At least 80% of those 65 years old and over suffer from one chronic disease and of those, as many as 40% may suffer from two or more chronic diseases. In one recent study (Anderson RJ, Excerpta Medica 5:26, 1982) of 102 elderly hypertensive patients, it has been shown that almost 40% also suffered from degenerative joint disease (osteoarthritis), some 25 to 30% suffered from diabetes mellitus, 20% from congestive heart failure, angina, or cerebrovascular disease. Thus, multiple pathology in about 30 to 40% of the elderly is the rule, rather than the exception. Most often, elderly suffer from hypertension, and as many as 40 to 60% of elderly are thought to suffer from this problem, which is a risk factor for cardiovascular, cardiac and cerebrovascular problems and ought to be treated. Hypertension occurs more often in females than in males, an important conclusion, as the health, social and economic problems of the elderly, particularly those 70 years old and over are those of females. Females, among the very old, outnumber males by a ratio of 3:1.

The aging of the population 65 years old and over has many implications. For example, among those 65 to 74 years old who may be hospitalized, only 4% are referred to long term care upon discharge from the acute care hospital. However, among those 85 years old and over, almost 25% are referred to long term care.

The aging of the older population has other implications to health care. Chronic disabilities occur in 15% of the total US population, but in 66% of those 85 years old and older.

THE SITES OF CARE

About 5% of the elderly or 1.4 million are cared for in nursing homes. However, for every elderly nursing home resident there are already four adults living in the community of similar age afflicated with equally serious medical problems. In 1987, 8.8 million elderly live alone (those living alone make more medication errors). Sixty-seven percent of those are elderly widows and 14% other elderly females. Thus, females account for 81% of those living alone. Often lacking financial resources (about 20%), they may not be able to purchase their medication. Some studies have indicated that as many as 36% of the elderly may, at times, have problems purchasing their medication.

Elderly living in the community may be divided into one of four major categories:

1. Independent
2. Independence threatened
3. Independence delegated
4. Dependent

An elderly woman with osteoarthritis and/or asymptomatic coronary artery disease may be medically stable. However, she may lose "independent" status when coronary artery disease progresses or if osteoarthritis gets worse. She may then be unable to pursue activities of daily living, such as shopping, threatening her independence. Worsening of a disease process may occur more rapidly when medications which are needed are not available.

When independence is delegated, family caregivers often become responsible for the community-living patient. On the average, the caregiver's age is slightly more than 60 years of age and many, indeed, are as old as the patient being cared for. Often, "caregiving" involves 124 hrs/week. Caregivers, therefore, are often exhausted and depressed, needing themselves multiple medications.

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* *Also referred to as polypharmacy or multiple drug use.*

Dr. Lamy is Professor and Director, The Center for the Study of Pharmacy and Therapeutics for the Elderly, School of Pharmacy, Professor, Epidemiology & Preventive Medicine, School of Medicine, University of Maryland at Baltimore, Baltimore, MD 21201

PRESCRIBING FOR THE ELDERLY

Data are scarce. In one study (Br Med J 294:289, 1987), underreporting of medications was common and increased as the number of prescribed drugs increased. In general, it is felt that there is still a significant incidence of inappropriate prescribing for the elderly (J R Coll Phys 21:39, 1987). It is generally believed that community-living elderly use about three prescription drugs/day and possibly two non-prescription drugs. Drug use is probably highest in nursing homes.

Approximately 45% of patients over the age of 65 in US nursing homes are on five or more prescription drugs a day (Table I):

TABLE I
Prescription Drug Use

	Age/Location of Patient		
No of Rx Products	65+/NH (%)	65+ non-NH (%)	65− (%)
One	12.0	27.4	43.9
Two	14.0	21.5	25.1
Three	14.8	16.2	13.3
Four	14.3	11.6	7.3
Five or more	44.9	23.4	10.4

Six of the ten most often prescribed drugs for the older-old are cardiovascular drugs (antihypertensives, digoxin, potassium supplements). There are significant differences. Beta-blockers represent 17.8% of cardiovascular drug use for community-living elderly (over 35% for those less than 65 years of age) but only 4.4% for nursing home residents. Major tranquilizers represent 12.5% of all psychotropic drugs used for community-living elderly, but they account for almost 61% of all psychotropics used for nursing home residents (Table II):

TABLE II
Specific Drug Categories

Drug Category	65+/NH (%)	65+/ non-NH (%)	65− (%)
Cardiovasculars	4.4	17.8	35.2
Beta-blockers			
Ca antagonists	2.9	8.6	8.6
Vasodilators	29.5	26.5	16.2
Digitalis	29.2	12.5	5.4
Psychotropics			
Antipsychotics	60.5	12.5	14.8
Anti-anxiety agents	17.1	59.0	51.0
Antidepressants	12.3	16.0	18.1

The use of psychotropic drugs for nursing home residents is also mirrored in a listing of the top 8 drugs used (Table III):

TABLE III
The Most Often Prescribed Drugs

Rank	Over 65/NH	Over 65/ non-NH	Under 65
1	Digoxin	HCTZ/ triamterene	Codeine/APAP
2	Furosemide	Digoxin	Amoxicillin
3	Potassium Cl	Potassium Cl	Norethin/ethinyl
4	Dipyridamole	Nitroglycerin	HCTZ/triamterene
5	Nitroglycerin	Furosemide	Penicillin V Pot
6	Haloperidol	Dipyridamole	Ibuprofen
7	Thioridazine	Propranolol	Theophylline
8	HCTZ/ triamterene	Codeine/APAP	Estrogens

The two antipsychotics (haloperidol and thioridazine) which rank high in use for nursing home residents rank only 99th and 90th for community-living elderly.

Six of the top 12 diagnoses and the top 12 drug groups for patients over 65 in 1986 were cardiovascular, with the top 12 representing 54% of all diagnoses and 64% of all drug therapy (the two drug categories whose use increases with increasing age are the cardiovascular drugs and the nonsteroidal anti-inflammatory drugs). The leading individual drugs in three of these cardiovascular categories were (Table IV):

For osteoarthritis, Motrin was most often prescribed, followed by Naprosyn, Feldene, Clinoril, Indocin and aspirin. Amoxicillin was the most often prescribed drug for bronchitis, followed by Theo-Dur, ampicillin, Keflex and others. Timoptic was most widely prescribed for glaucoma.

TABLE IV
Diagnosis-Related Drug Use

Diagnosis	Most Often Prescribed
Essential Benign Hypertension	Dyazide Hydrochlorthiazide Aldomet Tenormin
Congestive Heart Failure	Lasix Lanoxin Digoxin Capoten
Hypertension with Heart Disease	Lanoxin Lasix Dyazide Digoxin

THE IMPACT OF CHRONIC DISEASES

Those over 65 (12% of the population) represented 25% of all patient visits in the US in 1986. Almost 162 million visits were by females and 105 million by males, the rest being unspecified. New drug therapy accounted for almost 91 million prescriptions, but there were over 254 million refill prescriptions (In contrast, for those under 65, new prescriptions outranked refill prescriptions). Indeed, it has been estimated that about 70% of all prescriptions for the elderly are for chronic care drugs (who receive 32% of all prescription drugs).

POSSIBLE FUTURE CHANGES

Major changes (and concomitant cost increases?) are anticipated in the field of hypertension management. For example, a committee of the American Society of Hypertension (ASH), chaired by Dr. Norman Kaplan, reported at the 1987 meeting in New York that selection of a diuretic in the step-care approach to the management of hypertension seems increasingly inappropriate and outdated. For most patients, treatment should begin with a single agent, selected empirically or on the basis of age, race, coincident conditions such as hyperglycemis or hyperlipidemia, or by renin profiling.

Among antihypertensive drugs, the use of ACE inhibitors and calcium antagonists is rising fast (in the overall market). For example, first-quarter (1987) sales for calcium antagonists were $146 million, up 24% from the same period in 1986.

ADVERSE DRUG REACTIONS

There is no agreement as to the frequency of adverse drug reactions. One study (N Engl J Med 304:638, 1981) showed that 36% of patients on a general medical service had an iatrogenic illness, often due to drugs. Another (N Engl J Med 291:824, 1974) showed that these undesirable reactions occur most often in patients receiving multiple drugs. Deaths attributed to drugs occurred at a rate of 2.4 per 1000 patients (J Allergy Clin Immunol 74:555, 1984). The FDA expects reports to increase sharply (in 1986: 57,000 reports, a ten-fold increase over the last 5 years, going to over 100,000 in a few years). Most involve well-known drugs. One-third of all ADR hospitalization reports involved elderly, as did over 50% of all death reports. Thus, elderly are more susceptible to adverse drug reactions and to their effects.

Drug interactions occur more often in elderly than in younger patients. They occur most often in long-term care institutions and in patients with multiple pathology receiving multiple drugs.

Importantly, most drug interactions and adverse effects are predictable and thus, avoidable. Among reasons for adverse effects and interactions are physiological and pathophysiological changes in the elderly (Table V), multiple drug use, mismanagement of drugs and poor supervision. Mismanagement of drugs can be expected to increase if new packaging technology is not funded. This is particularly important in view of the fact that the home care segment is the fastest-growing segment of health care for the elderly. According to the Royal College of Physicians, supervision of chronic care medications is poor, accounting for many adverse effects and, according to the College of Physicians, physicians do not participate in home care.

MONITORING OF DRUGS AND DRUG USE

Different levels of auditing and monitoring will probably be sought. Indeed, macro- and micro-levels should be used, since each can yield important results.

Macro-Level: Medicaid data, available on computer in many states, have in the past been successfully used to elicit epidemiological drug data. These can be expanded (as is done by the Maryland Pharmaceutical Association, for example) to seek specific drug data.

Importantly, it has been estimated that in the near future, almost 50% of the US population will be cared for in some type of managed care system. Most of these, in an effort at cost-containment, use large population computer data, many patient-specific. Linked to diagnosis or problem, selection of a specific drug can be audited. New trends need to be taken into consideration, for example in the hypertension field.

TABLE V
Age-Related Changes and Their Possible Effects on Action of Antihypertensives

Organ/System	Change with age	Possible Effect
Brain	Cerebral blood flow decreased by 25%	Use drugs that preserve cerebral blood flow.
	Cerebral autoregulation impaired.	Caution: hyperfusion (?), Stroke (?)
	Increased permeability of blood/brain barrier	Exaggerated CNS effects by lipid-soluble drugs: clonidine, methyldopa, metopropolol propranolol
Cardiovascular	A poor homeostatic system. Impaired control and vascular reactivity.	
	Deterioration of conducting system.	Caution: drugs that interfere with cardiac impulse (beta blockers).
	Between ages 20 & 80 a 90% loss of vessel elasticity & distensibility	Greater fall in BP with decrease in blood volume. Increased risk to hypotension, hypovolemia
	Baroreceptor sensitivity decreased.	Altered compensatory mechanism drug induced fall in BP.
	Vascular aging (aortic arch), attenuated betaadrenergic response, blunted postural reflexes, decreased body water, varicose veins, etc.	Increased risk to drug-induced orthostatic hypotension. Caution with diuretics, ganglionic blockers, vasodilators.
Renal	By age 80, GFR decreased by 25%. Renal blood flow by 50%. Tubular function decreased by 7% per decade	Ability to adjust sodium balance is decreased. Caution: sodium depleting drugs, reduced dietary intake. Increased danger to diuretic induced water intoxication, hyponatremia. May have to reduce dose of renally excreted drugs. Defective thirst mechanism and impaired renal concentrating ability: higher risk to dehydration.

Micro-level: It is most important that the function of the pharmacist, mandated federally to review nursing home patients' therapeutic regimens, be expanded to include home care patients. This function has been found economically and clinically effective by the Comptroller General, and has just been expanded by HCFA to include ICF patients (see attached).

LETTERS

Dear Dave:

The Baltimore VA Medical Center, Pharmacy Service, and the University of Maryland School of Pharmacy Center for the Study of Pharmacy & Therapeutics for the Elderly will co-sponsor the 5th Annual Conference on Therapeutic Dilemmas in the Geriatric Patient. This year's theme will be "Cognitive and Dermatologic Problems in the Aged." This conference will be held on Tuesday, April 19, 1988 from 8 a.m. to 4:45 p.m. at Martin's West. A copy of the tentative program is enclosed.

Sincerely yours,
John T. Jordan, R.Ph., M.S.
Chairman, Planning Committee

Lilly Digest Operating Stats for South East Pharmacies

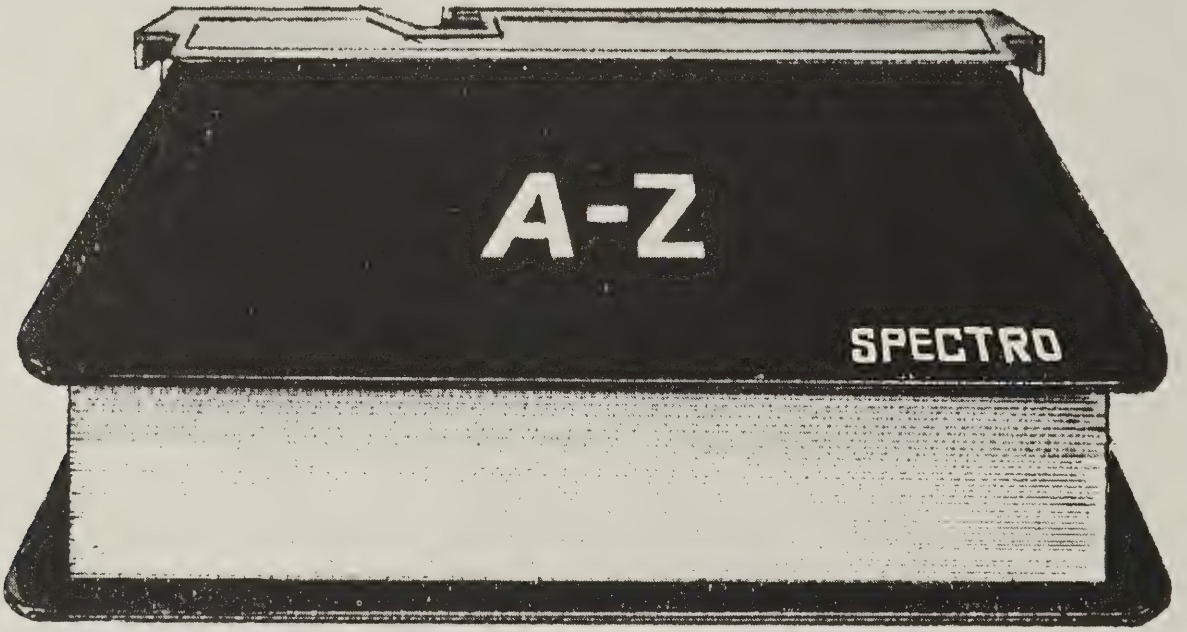
For: DELAWARE MARYLAND WEST VIRGINIA
D.C. SOUTH CAROLINA

LILLY DIGEST AVERAGES OF SELECTED OPERATING STATISTICS

AVERAGES PER PHARMACY	1986 *SOUTH ATLANTIC REGION* (162 Pharmacies)	1985 *SOUTH ATLANTIC REGION* (205 Pharmacies)	1986 Average *UNITED STATES* (1,245 Pharmacies)
SALES			
Prescription	$401,243— 69.3%	$366,345— 66.1%	$417,895— 63.9%
Other	177,442— 30.7%	188,064— 33.9%	235,698— 36.1%
Total Sales	$578,685—100.0%	$554,409—100.0%	$653,593—100.0%
COST OF GOODS SOLD	389,129— 67.2%	370,041— 66.7%	443,390— 67.8%
GROSS MARGIN	$189,556— 32.8%	$184,368— 33.3%	$210,203— 32.2%
EXPENSES			
Proprietor's or Manager's salary	$ 39,310— 6.8%	$ 35,977— 6.5%	$38,605— 5.9%
Employees' Wages	55,652— 9.6%	56,818— 10.2%	65,073— 10.0%
Rent	12,142— 2.1%	12,182— 2.2%	15,266— 2.3%
Miscellaneous Operating Expenses	62,788— 10.9%	59,850— 10.9%	73,460— 11.3%
Total Expenses	$169,892— 29.4%	$164,827— 29.8%	$192,404— 29.5%
NET PROFIT (before taxes)	$ 19,664— 3.4%	$ 19,541— 3.5%	$ 17,799— 2.7%
Add proprietor's withdrawal	39,310— 6.8%	35,977— 6.5%	38,605— 5.9%
TOTAL INCOME OF SELF-EMPLOYED PROPRIETOR (before taxes on income and profit)	$ 58,974— 10.2%	$ 55,518— 10.0%	$ 56,404— 8.6%
VALUE OF INVENTORY AT COST AND AS A PERCENT OF SALES			
Prescription	$ 42,290— 10.5%	$ 38,810— 10.6%	$ 43,296— 10.4%
Other	39,637— 22.3%	38,795— 20.6%	50,258— 21.3%
Total Inventory	$ 81,927— 14.2%	$ 77,605— 14.0%	$ 93,554— 14.3%
ANNUAL RATE OF TURNOVER OF INVENTORY	4.9 times	4.8 times	4.8 times
FLOOR AREA*	2,552 sq.ft.	2,573 sq.ft.	2,808 sq.ft.
SALES PER SQUARE FOOT*	$227.56	$215.83	$229.57
RENT PER SQUARE FOOT*	$ 4.76	$ 4.73	$ 5.44
NUMBER OF PRESCRIPTIONS DISPENSED			
New	15,248— 53.4%	14,243— 48.5%	16,080— 55.2%
Renewed	13,314— 46.6%	15,139— 51.5%	13,026— 44.8%
Total Prescriptions	28,562—100.0%	29,382—100.0%	29,106—100.0%
PRESCRIPTION CHARGE	$14.05	$12.47	$14.36
NUMBER OF HOURS PER WEEK			
Pharmacy was open	60 hours	61 hours	61 hours
Worked by proprietor	47 hours	50 hours	48 hours
Worked by employed pharmacist(s)	35 hours	37 hours	36 hours

* Based on averages of pharmacies that reported all data.
** Source: 1987 *Lilly Digest*

**22,000 Items.
Now that's healthy!**



You'll find in this book the most comprehensive listing of items available to your pharmacy. You'll also find we can deliver everything we list and do it within 24 hours.

This book is only Volume One in our library. Sales ideas, pricing, services, and time saving procedures, are all contained in the table of contents. Please call us.

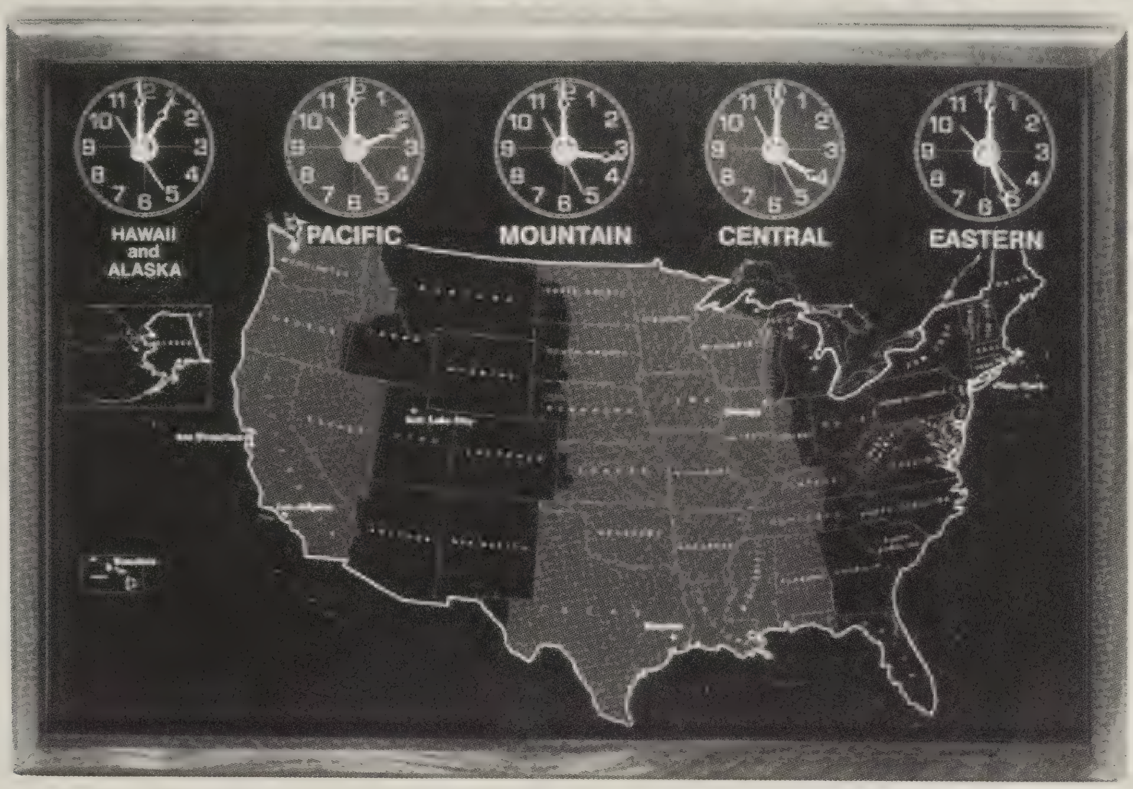
YOUR DIRECT SPECTRO REPS ARE:

District Wholesale Drug Corp.
Landover, MD 20785 301-322-1100
Loewy Drug Co., Inc.
Baltimore, MD 21237 301-485-8100

THE HEALTH CARE COMPANY

SPECTRO INDUSTRIES

SYNTEX WHOLESALER OF THE YEAR AWARDS FOR 1987.



Each of the award winners was presented with this handsome wall clock by a senior Syntex Sales Executive.

Winning a Syntex Wholesaler of the Year Award isn't easy.

We set our standards high with our first award six years ago, and we've kept them high ever since. We look at a lot of things – not just sales performance.

We use the same criteria for everyone, and we rely on the judgment of our Regional Directors and Field Sales Managers.

Past winners have told us that they value the recognition these awards represent. We're proud to recognize our sixth annual award winners – one from each of our sales regions. And we hope that next year your name will be there.

"LET'S HEAR IT FOR THE WINNERS."

1987 Regional Wholesaler Of The Year Award Winners

Mountain Pacific Region
McKesson Drug Company
Anaheim, CA

Gulf Central Region
McKesson Drug Company
Arlington, TX

Prairie Region
Dik Drug Company
Burr Ridge, IL

Ivy League Region
J. E. Goold and Company
Portland, ME

Dixie Region
Harris Wholesale Company
Atlanta, GA

Central Lake Region
Bergen Brunswig Drug Company
Fenton, MI

Mason-Dixon Region
District Wholesale Drug Company
Landover, MD

Northwest Frontier Region
McKesson Drug Company
Spokane, WA

Rocky Mountain Region
McKesson Drug Company
LaVista, NE

Blue Grass Region
L. S. DuBois Son & Company, Inc.
Paducah, KY

SYNTEX
DRUG
DISTRIBUTION
SYSTEM

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Announcing

The Independent Pharmacy Matching Service

NARD, in response to member requests, has established an exciting new member program called the Independent Pharmacy Matching Service (IPMS). IPMS is a national network for independent pharmacists who are seeking new employees or jobs for themselves, and it matches pharmacists who wish to buy or sell a pharmacy. The IPMS program will be launched at the 89th Annual NARD Convention in Las Vegas, NV, October 18-22, 1987.

How does it work? If you want to sell your pharmacy, buy a pharmacy, or locate and hire a new pharmacist or manager, complete an IPMS participation form and send it to NARD. Through an NARD-designed computer program, potential buyers are matched to pharmacy sellers and potential employees are matched to pharmacists looking for employment. If a match is found, both participants are informed of the mutually beneficial opportunity.

For example, let's say you want to sell your pharmacy. You complete the IPMS participation form and send it to NARD. When NARD receives an IPMS participation form from a potential buyer who is looking for a pharmacy in your geographical area, or with your sales volume, daily prescription activity, or other criteria, the buyer is given your name and phone number. No other pharmacy information is released. NARD also contacts you with the name and phone number of the interested buyer. After that, it's up to you and the buyer to set up a time to meet and close the deal.

What does it cost? At this first annual convention, the IPMS service is *free* for registrants who complete and return the annual registration form. Subsequently, the cost is only $25 per participation form. Please note that in order to participate, *you must be an NARD member.*

For further information on this exciting new program for independent retail pharmacists, contact NARD's Department of Professional Affairs toll free at 800-544-7447 between 1:00 and 5:00 p.m. Eastern time.

Independent Pharmacy Matching Service Participation Form

Please type or print legibly all requested information. NARD holds all IPMS submissions in strictest confidence.

PARTICIPANT INFORMATION

Name: ____________________

Pharmacy: ____________________

Mailing Address: ____________________

City/State/Zip: ____________________

Pharmacy Phone Number: ____________________

Home or Alternate Phone Number: ____________________

NARD Member Number: ____________________

I am seeking (check one only per form)
( ) to sell a pharmacy *(complete section one)*
( ) to buy a pharmacy *(complete section two)*
( ) to hire a new pharmacist/manager *(complete section three)*
( ) to obtain a new position *(complete section four)*

SECTION ONE: PHARMACY PRACTICE FOR SALE

Annual Sales Volume ________ Daily Rx Volume ________

Current Value of Inventory _____ Years in Business _____

Own or Lease Building _________ Selling Price _________

Please attach a 25-word description of your pharmacy.

SECTION TWO: LOOKING TO BUY A PHARMACY PRACTICE

Please attach a 25-word description of the pharmacy you wish to buy.

SECTION THREE: LOOKING TO HIRE A NEW PHARMACIST/MANAGER

Position ____________________

Starting Salary ____________ Benefits ____________

Years of Experience Required ____________

Please attach a 25-word description of the position and the ideal candidate's qualifications.

SECTION FOUR: LOOKING TO FIND A NEW POSITION IN INDEPENDENT RETAIL PRACTICE

Type of Position Sought ____________________

No. Years of Experience __________ In Retail __________

Year of Graduation ____________________

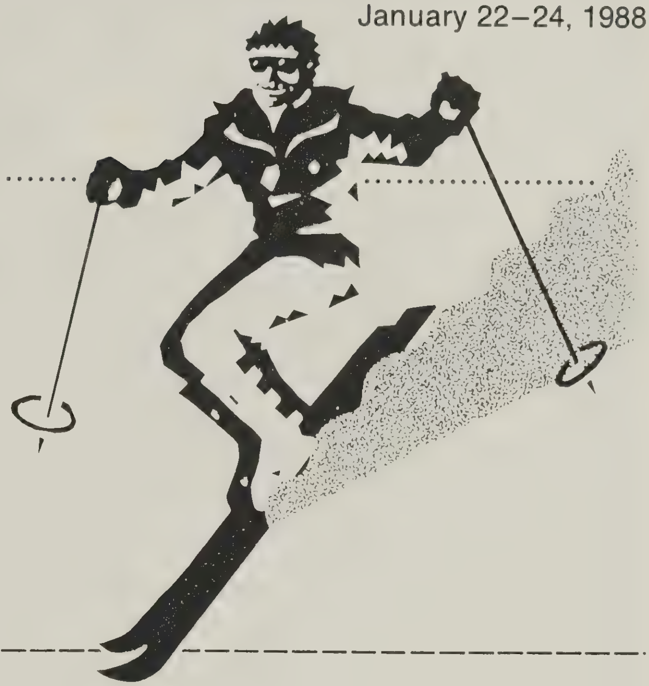
Please attach a 25-word description of yourself and your career objectives.

RETURN TO: DEPARTMENT OF PROFESSIONAL AFFAIRS
NARD
205 DAINGERFIELD ROAD
ALEXANDRIA, VA 22314

SKI WEEKEND GETAWAY

U of M School of Pharmacy Alumni
MD Pharmacists Association

January 22–24, 1988



SKI GREEK PEAK

LODGING AT THE RAMADA INN,
Binghamton, NY

LOOK WHAT'S INCLUDED!

ROUNDTRIP TRANSPORTATION:
via lavatory equipped motorcoach.

2 NIGHTS ACCOMMODATIONS AT THE RAMADA INN BINGHAMTON:

- ▶Deluxe, comfortable rooms featuring color TV and individual climate control.
- ▶Indoor pool and Scandinavian saunas.
- ▶3 great night spots on the premises:
  - —ESPRIT CLUB: Dance the night away at Binghamton's largest and most popular dance club where you will be mesmerized by the spectacular light and sound show.
  - —IMAGES: This fireside adult entertainment lounge is the perfect place to listen to your favorite music, enjoy billiards, darts, old-time movies, shuffle board, video games, fresh popcorn, deli sandwiches and your favorite drinks.
  - —JENNIFERS LOUNGE: A cozy night spot featuring big screen entertainment.

4 SCRUMPTIOUS BUFFETS:

- ▶2 hearty "all you can eat" breakfasts
- ▶2 delicious dinners: four course sit down dinner on Saturday featuring your choice of "King Cut" Prime Rib or Boneless Breast of Chicken and an International Steamship buffet on Sunday.
- ▶Saturday Evening Dining Option . . . Exchange your buffet coupon for a credit towards dinner in Jennifer's restaurant choosing from the regular menu.

DANCING, PARTIES AND NONSTOP FUN!!

- ▶Welcome reception upon arrival with refreshments.
- ▶2 Aprés Ski Parties on Saturday and Sunday afternoons feature 99¢ drink prices, hot and cold hor d'oeuvres with free wine on Sunday.
- ▶Unbeatable nightlife alternatives in Esprit, Images and Jennifers.
- ▶Midnight horror film on Saturday night in Jennifers.

SKIER SERVICES:

- ▶Unlimited free ski lessons at Greek Peak each day with the purchase of a lift ticket.
- ▶Daily transfers to Greek Peak / Availability of a Tours de Sport Ski Rental Shop in the hotel.

ALSO INCLUDED:

- ▶Transfers provided on Sunday to shopping, ice-skating* and roller-skating,* horseback riding,* and horse drawn sleigh rides.*
- ▶Services of Tours de Sport's on-site staff / Tour Guide on bus / Itinerary / Late checkout / Taxes & gratuities.

TOURS DE SPORT

FOR MORE INFORMATION CONTACT:
Brian T. Sanderoff: 752-3473 D
Beverly Litsinger: 727-0746 D

PRICES PER PERSON:
4 in a room—$124.00
3 in a room—$139.00
2 in a room—$154.00

MAKE CHECKS PAYABLE TO:
Maryland Pharmacists Association

PAYMENT SCHEDULE:
$35.00 due by 11/05/87
Final balance due by 12/25/87

BUS DEPARTURE SCHEDULE:
The bus will depart at 6:00 PM on Friday January 22, 1988 from Security Square Shopping Center, Security Blvd.

POSSIBLE C.E. PROGRAM AVAILABLE—ASK BRIAN!

NOT INCLUDED IN TOUR PRICE:

- ▶Discount lift tickets** sold right in hotel.
- ▶Ski Rentals** (skis, boots & poles) for the entire weekend . . . only $15 per person.

*** Payment for these options will be collected at the hotel (CASH ONLY PLEASE).*

SKI GREEK PEAK

CENTRAL NEW YORK'S LARGEST SKI RESORT

23 slopes and trails from beginner to expert / 900′ vertical rise / 8 lifts / Longest trail 1.5 miles / 27 miles of cross country trails / 85% snowmaking / Certified ski school and ski patrol / Base lodge with restaurant, bar and ski shop.

Through their experience as pharmacists, we explored your concerns.

Through their insights as panelists, we discovered new ideas.

The members of our 1987 Pharmacy Consultant Panel spoke from personal experience. But their ideas and concerns spanned the breadth of our profession. We thank them for sharing their wisdom, experience and advice. Most of all, we look forward to putting their ideas to work to serve pharmacy professionals better.

Standing Left to Right:

Jack R. Cole, Pharmacist
Dean, College of Pharmacy
University of Arizona
Tucson, AZ

Reed Rosling, Pharmacist
Vice President, Hospital Sales
Bergen Brunswig Drug Company
Orange, CA

Thomas M. Ryan, Pharmacist
Vice President, Pharmacy Operations
Consumer Value Stores
Woonsocket, RI

William G. Thien, Pharmacist
Vice President
Health Services & Pharmacy Operations
Walgreen Drug Stores
Deerfield, IL

Darwyn J. Williams, Pharmacist
President
Williams Drugs Inc.
Webster City, IA

Seated Left to Right:

John H. Vandel, Pharmacist
President
Vandel Drugs, Inc.
Torrington, WY

Marily Rhudy, Pharmacist
President
Continental Pharmacy, P.A.
Topeka, KS

Thomas R. Temple, Pharmacist
Executive Director
Iowa Pharmacists Association
Des Moines, IA

M. Patricia Lee, Pharmacist
Director of Pharmacy
UCSD Medical Center
San Diego, CA

Upjohn

Not pictured; Bernard Mehl, Pharmacist, Director of Pharmacy Mount Sinai Hospital, New York, NY
John J. Piecoro, Jr., Pharmacist, Associate Director Clinical Services Chandler Medical Center, Lexington, KY

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New face of pharmacy

by Jim Dickinson

It used to be that folks could tell the best pharmacy in town by the quality of its ham sandwiches. It was a neighborhood institution, inhabited by teenagers.

Only Norman Rockwell can remember those days, and he's dead.

Then the pharmacy came to be a hidey-hole in the back of a big store full of general merchandise, and it was no longer an institution.

The public, which makes and breaks social institutions, a few years ago accorded pharmacists (as distinct for the hidey holes in which they work) No. 2 status behind clergy as its most-trusted professionals.

And then came dispensing physicians, HMOs, mail-order options and the syndrome that's become known as "the graying of America."

Where the average Joe Citizen places pharmacy is in all of this is questionable. But when he takes a look, he will surely see that pharmacy has a new face.

It's not the kindly, "old doc" face of Rockwell paintings. It's a businesslike, professional face and it belongs to a highly knowledgeable expert who has been toughened by the years since Rockwell's time.

This face of pharmacy may be white or black (or, increasingly, yellow), young or old, male or female (more likely female, if young).

But whatever it is, it's not likely to be kindly.

Today's pharmacist is under siege, and the face that's shown to the public is likely to show it.

It's "Operation Fight-Back" time, as the boom in PSAO (pharmacy service administrative organization) activity across the country is showing. The number of third-party plan beneficiaries covered by PSAO programs of one kind or another is increasing at a 64% annual rate.

Put another way, 4.3 million Americans get their third-party program prescriptions through a contract that allows freedom-of-choice of participating independent pharmacy, rather than be locked into a single chain, HMO or mail-order pharmacy.

It isn't unfettered open access to anything, and there are price controls. But at a 64% growth rate, it's evidence of pharmacy's collective fight-back.

Five years ago, the PSAO idea would have been unthinkable. First, every legally-wise person pharmacists consulted said PSAOs would be illegal under the anti-trust laws. Second, it was conventional wisdom that pharmacy was just too plain divided to get its act together for such a concept.

Two Justice Department advisory letters last year changed that, and at a time when many people were gloomily predicting the extinction of independent pharmacy by the year 2001, the PSAO revolution began.

Today there are 53 active PSAOs, the latest being the national RxNet, a subsidiary of the National Association of Retail Druggists. RxNet serves as a national clearing house and marketing organization for the other, affiliated PSAOs in the states.

A central theme of the PSAO, whether national, state or local, is quality of care—hands-on, personal attention by a live pharmacist who knows his or her patients, and who keeps patient profiles for effective drug utilization review.

Many PSAO plans actually pay the pharmacist to *not* dispense, thereby curbing waste (the incentive in capitation plans can be to share surpluses in the pool at the end of the contract term, helping focus pharmacists on the need to question irrational prescribing through the PSAO).

This is, admittedly, controversial. Many pharmacists do not yet belong to PSAOs, and many who do simply hate the very idea of capitation. Certainly, contracts that leave pharmacy with all the risk are not worth signing up for, especially when the underlying data upon which that risk is based have holes in them.

And some pharmacists would rather pay no attention to DUR, and leave all accountability with the prescriber.

Three of those 53 PSAOs have already gone bankrupt, and many more are likely to fail for want of getting (or keeping) a single contract. Pharmacists can be impatient, and not give their PSAO time to get on its feet or prove itself, and that syndrome will kill some PSAOs.

It's early days yet, for the PSAO movement. Its growth has been electric, and the results are not yet in. But a 64% annual growth rate in an environment in which managed health care plans and HMOs are in desperate financial turbulence is a ringing endorsement of the way pharmacy has begun to fight back.

The face of pharmacy has changed.

This feature is presented on a grant from G. D. Searle & Co., in the interests of promoting the open discussion of professional issues in pharmacy. G. D. Searle & Co. accepts no responsibility for the views expressed herein as they are those of the author and not necessarily those of G. D. Searle & Co.

Save this Patient Resource Information: AIDS Hotlines by States

State Departments of Health: AIDS Information

Alabama	(205) 261-5131
Alaska	(907) 561-4406
Arizona	(602) 255-1203
Arkansas	(501) 661-2395
California	(916) 445-0553
Colorado	(303) 331-8320
Connecticut	(203) 549-6789
Delaware	(302) 995-8422
District of Columbia	(202) 332-AIDS
Florida	(904) 488-2905
Georgia	(800) 342-2437
Hawaii	(808) 735-5303
Idaho	(208) 334-5944
Illinois	(312) 871-5696
Indiana	(317) 633-8406
Iowa	(515) 281-5424
Kansas	(913) 862-9360
Kentucky	(502) 564-4478
Louisiana	(504) 342-6711
Maine	(207) 289-3747
Maryland	(301) 945-AIDS
Massachusetts	(617) 727-0368
Michigan	(517) 335-8371
Minnesota	(612) 623-5414
Mississippi	(601) 354-6660
Missouri	(816) 353-9902
Montana	(406) 444-4740
Nebraska	(402) 471-2937
Nevada	(702) 885-4988
New Hampshire	(603) 271-4487
New Jersey	(609) 588-3520
New Mexico	(505) 984-0911
New York	(518) 473-0641
North Carolina	(919) 733-3419
North Dakota	(701) 224-2378
Ohio	(614) 466-4643
Oklahoma	(405) 271-4061
Oregon	(503) 299-5792
Pennsylvania	(717) 787-3350
Rhode Island	(401) 277-2362
South Carolina	(803) 734-5482
South Dakota	(605) 773-3364
Tennessee	(615) 741-7247
Texas	(512) 458-7504
Utah	(801) 538-6191
Vermont	(802) 863-7240
Virginia	(804) 786-6267
Washington	(206) 361-2914
West Virginia	(304) 348-5358
Wisconsin	(608) 267-3583
Wyoming	(307) 777-7953

"RETURN GOODS POLICY MANUAL"

New third edition contains the return goods policies of over 150 pharmaceutical manufacturers in a standard format. The policies are in a three ring binder to allow for updates and additions.

The ***RETURN GOODS POLICY MANUAL*** provides information on:

*who to contact if a sales representative is not available

*company addresses and phone numbers

*what items are and are not returnable

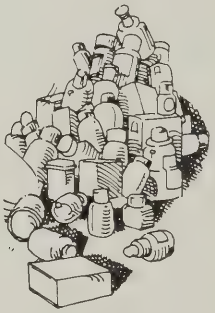
*the procedure for returning items

*the type of compensation to the pharmacy, i.e. credit or exchange

*transportation charges

*company disclaimers

**and much more.



Please allow 4 to 6 weeks for delivery.

Please send me _____ copy(ies) of the ***RETURN GOODS POLICY MANUAL*** at $30.00 each (includes postage and handling).

_____ check enclosed

____ VISA ____ Mastercard

#_______________________________

Exp. Date_______________________________

Name _______________________________

Address _______________________________

____

Mail to:

Maryland Pharmaceutical Association
650 W. Lombard Street
Baltimore, Maryland 21201

WHY BUY JUST A BOOK

. . . when you can subscribe to *USP DI?*

USP DI® – a clinically relevant drug-use, patient education information service providing health care professionals with continuously updated, unbiased drug data throughout the year.

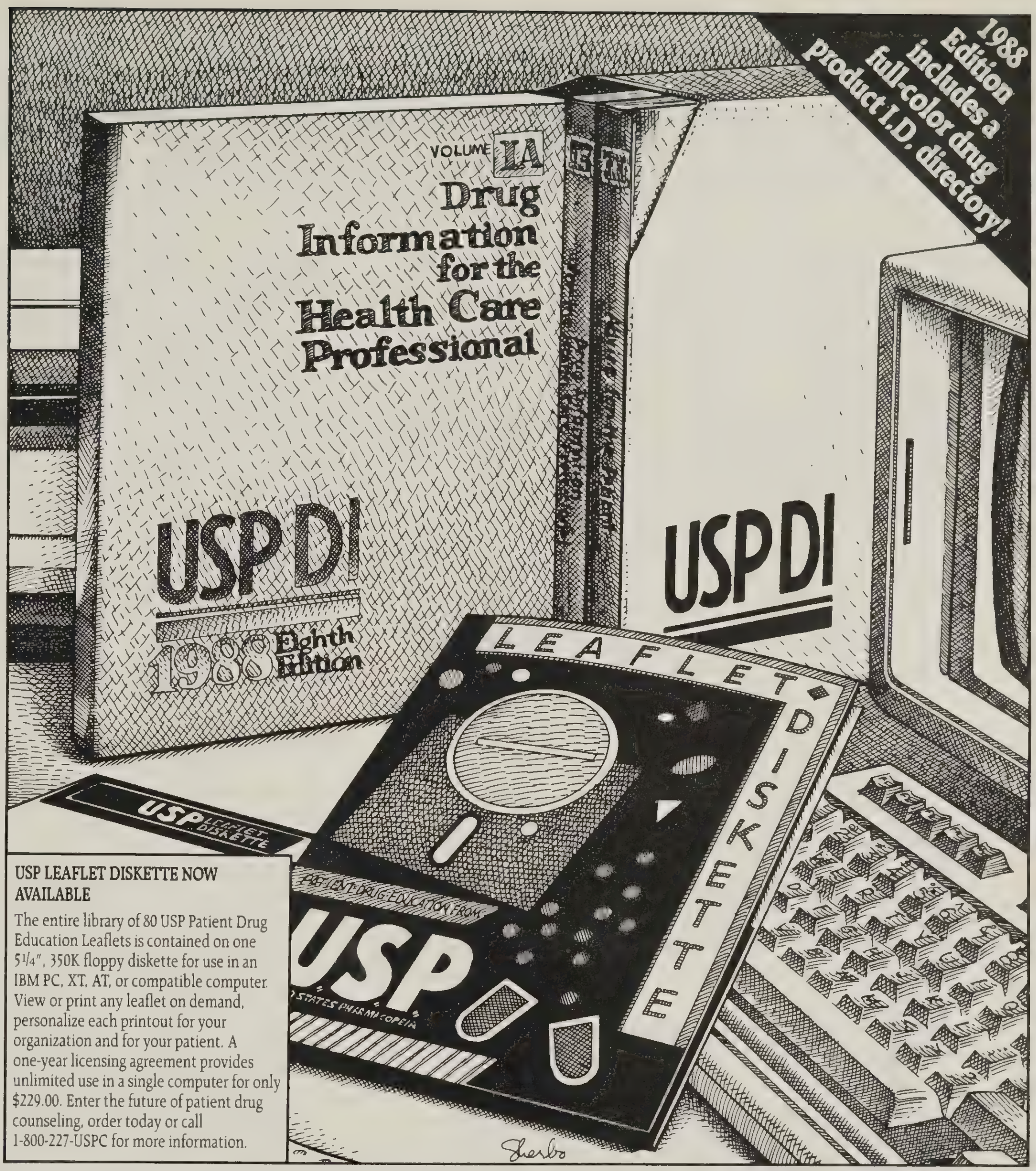
Bimonthly *Updates* provide new and revised information in a bound, cumulatively indexed, "newsletter" format, avoiding the inconvenience of replacing, or worse, losing pages.

FEATURES OF 1988 EDITION:

- 16-page drug product I.D. directory. Includes approximately 800 color photographs of the most widely used medications, both brand and generic.
- Indications separated into "accepted" and "unaccepted" sections in each drug monograph.
- USP legal requirements for quality, labeling, storage, and packaging important to the dispensing situation.
- Patient drug-use counseling guidelines.

Start a calendar year subscription to the *USP DI*, two-volume set (three books) and six *Updates* before January 29, 1988 at the special price of $95.00 (regularly $115.00).

Continue your subscription annually at the lower renewal rate (billed each December) so you are assured of receiving revised main volumes and a continuous flow of *Updates*.



1988 Edition includes a full-color drug product I.D. directory!

USP LEAFLET DISKETTE NOW AVAILABLE

The entire library of 80 USP Patient Drug Education Leaflets is contained on one 5¼", 350K floppy diskette for use in an IBM PC, XT, AT, or compatible computer. View or print any leaflet on demand, personalize each printout for your organization and for your patient. A one-year licensing agreement provides unlimited use in a single computer for only $229.00. Enter the future of patient drug counseling, order today or call 1-800-227-USPC for more information.

ORDER FROM YOUR STATE ASSOCIATION BEFORE JANUARY 29 AND SAVE $20.

Get more than just a "book".

☐ Yes! I want to join the *USP DI* service at the special price of $95.00 for the 1988 calendar year ($20.00 off the regular price).

☐ Add $5.00 to each subscription for UPS (or equivalent) delivery of the main volumes.

☐ YES! Send me one USP Leaflet Diskette with a one year licensing agreement for $229.00. (Inquire about quantity discounts.)

The 1988 *USP DI* is scheduled for release in January 1988. Please allow 4 - 6 weeks for book rate postal delivery.

SEND
ORDER
TO: **Maryland Pharmaceutical Association**
650 W. Lombard Street
Baltimore, Maryland 21201

FULL MONEY BACK GUARANTEE! If for any reason, you are not satisfied after receipt, return your purchase (in resaleable condition, or with Diskette envelope unopened) within 30 days for a full refund.

☐ Enclosed is my check or money order payable to USPC for $ ________________.
(PA residents add 6% sales tax, MD residents add 5% sales tax.)

☐ Charge my: ☐ MasterCard ☐ VISA

Acct. # ________________ Exp. Date ________

Signature ________________

Name ________________

Pharmacy ________________

Address ________________

City ________ State ________ Zip ________

(______) ________________
Telephone

OSTEOPOROSIS FACT SHEET

- Osteoporosis, which means porous bone, is a condition characterized by an exaggerated loss of bone tissue and an increased susceptibility to fractures.
- 24 million Americans are affected by this major public health problem.
- Last year alone, the national medical and lost-productivity costs of osteoporosis and osteoporotic fractures were estimated at $7–10 billion.
- This bone-thinning disorder is responsible for 1.3 million bone fractures annually. The hip, spine and wrist are the most common sites of osteoporosis-related fractures.
- A "silent disorder," osteoporosis may first signal its presence by a hip or wrist fracture, significant back pain, or a loss of height.
- A woman's likelihood of developing osteoporosis increases with age because the leading cause of the disorder is a deficiency of estrogen. Other risk factors include early menopause (before age 45); extreme immobility; chronically low intakes of calcium; being very thin or small-boned; smoking; and excessive consumption of alcohol or caffeine.
- Annually, 247,000 hip fractures occur in persons age 45 years and older. Among victims who were living independently prior to the fracture, 15–25 percent were in long-term care institutions a year after the bone fracture.
- Recent studies suggest that about 40 percent of all women will have at least one spinal fracture by 80 years of age. Vertebral fractures often heal unevenly, leaving the individual bent over with a curved back or "dowager's hump."
- Osteoporosis is associated with the prolonged use of certain medications (e.g., cortisone and similar drugs) and is a known complication of a number of medical conditions including endocrine disorders (such as an overactive thyroid) and rheumatoid arthritis.

Prevention

- Because the number of older Americans in our society is rapidly increasing, awareness and prevention of osteoporosis are extremely important.
- One popularly held misconception is that our skeletons are inert and lifeless. Bone is actually a living structure that changes in response to the loads and stresses of everyday living. This is why maintaining a healthy lifestyle is essential.
- Some ways of maintaining healthy bone tissue include:
  - Eating a well-balanced diet rich in calcium,
  - Exercising regularly, and
  - Limiting alcohol, caffeine and smoking
- Scientists believe that healthy lifestyles may have the greatest impact on bone in early life (prior to age 35), when peak bone mass is developing. A strong skeleton may reduce the risk of fractures in later life.
- Women approaching menopause should discuss the benefits and risks of estrogen replacement therapy with their physicians. Oral estrogens retard bone loss and are FDA-indicated for the treatment of osteoporosis.

Revised Osteoporosis Booklet Now Available From NIAMS

Osteoporosis: Cause, Treatment, Prevention, a newly revised brochure, is available from the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Osteoporosis is the major underlying cause of bone fractures in postmenopausal women and older persons in general, leading to an estimated 1.3 million fractures each year in people over 45 years of age. The disorder costs the country over $6 billion annually.

The 44-page publication explains what osteoporosis is and discusses several possible risk factors. It describes ways to prevent and possibly treat the disease; and it reviews some of the current research related to osteoporosis.

In particular, the brochure describes measures that may prevent or at least slow down the development of osteoporosis. These are: estrogen replacement therapy—the only measure for which there is well-documented evidence of effectiveness—as a possibility for women going through or past menopause; increased calcium intake through diet and, if necessary, supplements; adequate vitamin D, especially for people who get very little sunlight; regular, weight-bearing exercise such as walking; and prevention of accidents and hazards that lead to fractures.

To get a single copy, send a business-sized, self-addressed envelope (about 4″ by 9½″) with 44¢ postage to:

Osteoporosis booklet
NIAMS/National Institutes of Health
Bldg. 31, Rm 9A04
Bethesda, MD 20892

Quantities are available from this address as follows: 10 copies for $2 postage and handling; 25 copies for $5; or 50 copies for $10. Checks or money orders must be made out to "AMS Clearinghouse." All orders must be prepaid.

Organizations may reprint the booklet for their own use.

Heller Retires from U.S.P.

William M. Heller has announced his decision to step down as Executive Director of USP at the close of the USPC Quinquennial Meeting on March 10, 1990.

USPC Board of Trustees Chairman John T. Fay has appointed a Search Committee for Dr. Heller's successor. Chaired by USPC President Arthur Hull Hayes, Jr., the Committee consists of Board members J. Richard Crout and James T. Doluisio, and Ralph F. Shangraw, a member of the USP Committee of Revision.

Ideally, the executive director-designate should assume the position in the fall of 1988 so that he or she can take complete charge of planning the 1990–1995 administration of the Pharmacopeial Convention. However, a person already familiar with the pharmacopeial organization may prefer to shorten the lead-time.

The person selected will report directly to the Board of Trustees, along with the current Executive Director. He or she is expected to consult widely both nationally and internationally among the constituencies of this unique organization to obtain views of its current and potential obligations and services. The classifications of experts and the number of experts needed in each classification must be determined one year prior to the 1990 Meeting. The review of credentials for over 1000 candidates for the 1990–1995 USP Committee of Revision is anticipated; nominees must be selected by the Nominating Committee no later than 60 days prior to the Meeting. Resolutions must be formulated to gain a sense of the support for existing and potential functions by the members of the multi-disciplinary Pharmacopeial Convention. The Agenda and conduct of the meeting must be planned. In these activities the Designate will have primary responsibility, working with the current Executive Director. In mutual agreement with the current Executive Director and with the approval of the Board, the Designate may also assume some current staff administrative functions prior to the Quinquennial Meeting.

After 10 years on the USP Committee of Revision, Heller joined the USP staff in 1968 as executive director-designate, and became executive director in 1970. During his tenure the merger of the *United States Pharmacopeia* and the *National Formulary*, previously owned by the American Pharmaceutical Association, was accomplished. In-house laboratory and phototypesetting facilities were developed. The internationally utilized collection of Reference Standard materials was increased from 236 in 1970 to over 1000 articles in 1987. The *USP DI* System of drug information references for health professionals and patient education materials for consumers, the most comprehensive and widely used data base for patient information in the world, was created. An annual Dictionary of Drug Names was developed to serve as the standard nomenclature reference.

The Headquarters staff of 140 persons (1987) serves as the secretariat to the Committee of Revision (95 persons, 1987) and Advisory Panels (approximately 350 persons, 1987) in the writing of *USP-NF* and *USP DI*. A modern microanalytical laboratory (20 chemists, 1987) in the Headquarters is instrumental in assuring the integrity of over 1,000 USP Reference Standards used world-wide.

A new 68,600 square foot Headquarters Building is scheduled for occupancy in the summer of 1989.

Candidates for the position should express their interest to: Arthur Hull Hayes, Jr., M.D., Chairman, Search Committee, 12601 Twinbrook Parkway, Rockville, MD 20852.

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The Prescription Network of Maryland

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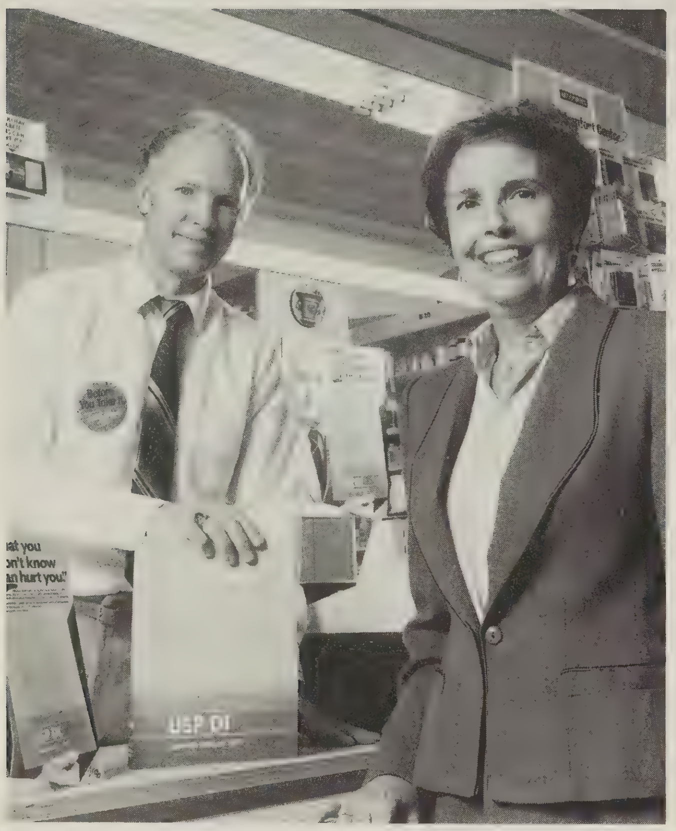

MPhA President Lee Ahlstrom and Estelle Cohen display the Advice to the Patient portion of the USP-DI in his pharmacy in Dundalk as part of the public education campaign sponsored by MPhA, USP and WBAL-TV. Estelle is a consumer member to the USP Board, a former consumer member of the Maryland Board of Pharmacy, and was recently named as Honorary President by the Baltimore Metropolitan Pharmaceutical Association for her work in inspiring the campaign for Maryland.

Oscar Schapiro was named the 1987 Bowl of Hygeia Award recipient from the State of Maryland given by the A. H. Robins Company for his work in public service. Oscar is an emergency medical technician and he and his wife Norma have a pharmacy in Phoenix, Maryland.

The Prescription Network of Maryland, a subsidiary of the MPhA, has retained a marketing consultant, Mr. Charles Schmidt from the firm of Health Systems Plus, to market the newly formed pharmacy network. He has already made valuable contacts for pharmacists and prescription program contracts are expected to follow soon.

The Frederick County Pharmaceutical Association recently held elections and the new officers for 1988 are: (from Left to right) Owen Hillberg, Third Vice President; Jim Rutten, Program Chairman; Kathy Mantine, President; Dominique Newcomer, Secretary-Treasurer; Bob Brant, First Vice President; and (not Shown) Suzanne Keiffer, Second Vice President.

MSHP Annual Seminar

MSHP President-elect, Paul Jeffrey (left) presents Larry Green with the Pfizer Hospital Pharmacist of the Year Award at the annual MSHP Awards Banquet. The Annual Seminar was held in Williamsburg, Virginia with record attendance.

Rebecca S. Finley (left) was the recipient of the prestigious MSHP Purdum Award for the 1987. Her proud mother was on hand to witness the presentation.

Featured Banquet Speaker, Clif J. Latiolais, spoke on corporate America's influence on healthcare services and pharmacy practice.

MSHP President Jan Iwata receives the Squibb Past President's Award at the annual banquet.

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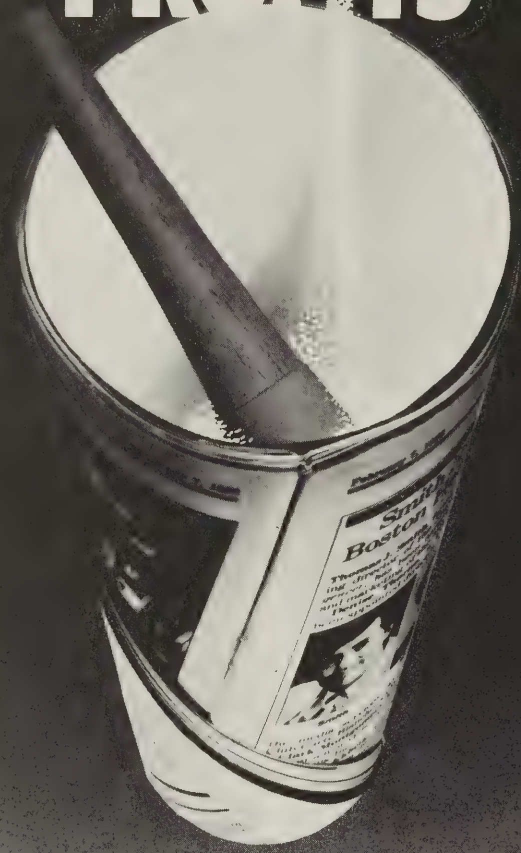

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Maryland Society of Hospital Pharmacists Meetings

MARK YOUR CALENDARS, PLEASE:

The 1987–1988 MSHP Roster of Monthly Programs is under development. Please note the following dates and sites on your calendars:

NOVEMBER 12, 1987	University of Maryland Medical System
DECEMBER 3, 1987 (note *first* Thurs!)	Franklin Square Hospital
* JANUARY 14, 1988	* SPECIAL AGENDA at a Non-Hospital Site (TBA) will feature Officers' Installation *
FEBRUARY 11, 1988	—TBA (To Be Announced)
MARCH 10, 1988	—TBA (To Be Announced)
APRIL 14, 1988	Mercy Hospital
MAY 12, 1988	Johns Hopkins Hospital

PHARMACY SCHOOL NATIONAL TOLL FREE PHONE LINE. The school of Pharmacy has acquired a new national toll free phone for Admission and Registrar department. The number is 1-800-852-2988, you may call between the hours of 9:00 a.m. and 5:00 p.m., Monday–Friday. The new 1988 Pharmacy School catalog is now available for order.

calendar

December 3—MSHP regular meeting
Dec. 13—AZO Breakfast seminar. Pikesville Holiday Inn
January 4—State Legislature Begins 1988 session
Jan. 17—AZO Breakfast seminar Pikesville Holiday Inn
Jan. 22–24—MPhA and Alumni Assn. Ski Weekend
February 7—MPhA Mid Year Meeting—Annapolis
Feb. 17—AZO Evening dinner seminar Suburban House Pikesville
March 12–16—APhA Annual Meeting—Atlanta

Every Sunday Morning at 6:30 a.m. on WCAO-AM and 8:00 a.m. on WXYZ-FM listen to Phil Weiner broadcast the Pharmacy Public Relations Program "Your Best Neighbor," the oldest continuous public service show in Baltimore.

"Rx" license plates can still be ordered through the Association. When you receive your license renewal form, contact Mary Ann at the Association Office (727-0746) for details. The plates also say "Maryland Pharmacists Association" in addition to Rx and number. This offer is open to members and their families only.

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